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Voss

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(54) **ARTICULATING SUTURING DEVICE**

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(52) **U.S. Cl.**

CPC ***A61B 17/04*** (2013.01); ***A61B 17/0057*** (2013.01); ***A61B 17/0469*** (2013.01); ***A61B 17/0482*** (2013.01); ***A61B 17/0485*** (2013.01); *A61B 2017/00623* (2013.01); *A61B 2017/00663* (2013.01); *A61B 2017/00809* (2013.01); *A61B 2017/00818* (2013.01); *A61B 2017/0472* (2013.01); *A61B 2017/0477* (2013.01); *A61B 2017/0496* (2013.01); *A61B 2017/06042* (2013.01); *A61B 2017/06052* (2013.01)

(58) **Field of Classification Search**

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

287,046	A	10/1883	Norton
438,400	A	10/1890	Brennen
556,082	A	3/1896	Boeddinghaus
1,088,393	A	2/1914	Backus

(Continued)

FOREIGN PATENT DOCUMENTS

AU	2003297432	7/2004
CA	2 339 060	2/2000

(Continued)

OTHER PUBLICATIONS

Grossman, W., Cardiac Catheterization and Angiography, 3rd Ed., Lea & Febiger, Philadelphia, pp. 1-49, 52-247. 1986.

(Continued)

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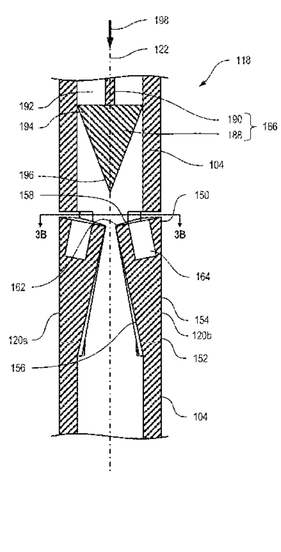
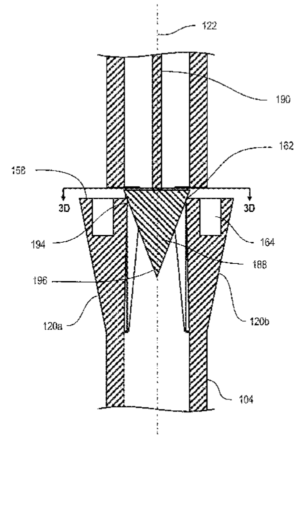
(57) **ABSTRACT**

An apparatus for closing an opening in a body tissue. The apparatus includes a shaft, a plurality of arms, and an expander. The arms each extend between a proximal end and a distal end. The distal end of each arm is hingedly attached to or integrally formed with the shaft. The arms are laterally spaced apart from each other. The arms are movable between a retracted configuration, in which the arms are each aligned along the shaft, and a deployed configuration, in which the proximal end of each arm pivots respectively about the distal end of the arm so as to extend laterally away from the shaft. The expander is positioned within the shaft, and movement of the expander causes the arms to move between the retracted and deployed configurations. Methods of using the apparatus are also included.

11 Claims, 57 Drawing Sheets





(56) **References Cited**

U.S. PATENT DOCUMENTS

1,123,290	A	1/1915	Von Herff
1,331,401	A	2/1920	Summers
1,596,004	A	8/1926	De Bengoa
1,647,958	A	11/1927	Ciarlante
1,880,569	A	10/1932	Weis
2,087,074	A	7/1937	Tucker
2,210,061	A	8/1940	Caminez
2,254,620	A	9/1941	Miller
2,316,297	A	4/1943	Southerland et al.
2,371,978	A	3/1945	Perham
2,453,227	A	11/1948	James
2,583,625	A	1/1952	Bergan
2,684,070	A	7/1954	Kelsey
2,755,699	A	7/1956	Forster
2,910,067	A	10/1959	White
2,944,311	A	7/1960	Schneckenberger
2,951,482	A	9/1960	Sullivan
2,969,887	A	1/1961	Darmstadt et al.
3,015,403	A	1/1962	Fuller
3,113,379	A	12/1963	Frank
3,120,230	A	2/1964	Skold
3,142,878	A	8/1964	Santora
3,209,754	A	10/1965	Brown
3,482,428	A	12/1969	Kapitanov et al.
3,494,533	A	2/1970	Green et al.
3,510,923	A	5/1970	Blake
3,523,351	A	8/1970	Filia
3,586,002	A	6/1971	Wood et al.
3,604,425	A	9/1971	Le Roy
3,618,447	A	11/1971	Goins
3,677,243	A	7/1972	Nerz
3,757,629	A	9/1973	Schneider
3,805,337	A	4/1974	Branstetter
3,823,719	A	7/1974	Cummings
3,828,791	A	8/1974	Santos
3,856,016	A	12/1974	Davis
3,874,388	A	4/1975	King et al.
3,908,662	A	9/1975	Razgulov et al.
3,926,194	A	12/1975	Greenberg et al.
3,939,820	A	2/1976	Grayzel
3,944,114	A	3/1976	Coppens
3,960,147	A	6/1976	Murray
3,985,138	A	10/1976	Jarvik
4,007,743	A	2/1977	Blake
4,014,492	A	3/1977	Rothfuss
4,018,228	A	4/1977	Goosen
4,047,533	A	9/1977	Perciaccante et al.
4,064,881	A	12/1977	Meredith
4,112,944	A	9/1978	Williams
4,153,321	A	5/1979	Pombrol
4,162,673	A	7/1979	Patel
4,169,476	A	10/1979	Hiltebrandt
4,192,315	A	3/1980	Hilzinger et al.
4,201,215	A	5/1980	Crossett et al.
4,204,541	A	5/1980	Kapitanov
4,207,870	A	6/1980	Eldridge
4,214,587	A	7/1980	Sakura, Jr.
4,215,699	A	8/1980	Patel
4,217,902	A	8/1980	March
4,273,129	A	6/1981	Boebel
4,274,415	A	6/1981	Kanamoto et al.
4,278,091	A	7/1981	Borzone
4,317,445	A	3/1982	Robinson
4,317,451	A	3/1982	Cerwin et al.
4,318,401	A	3/1982	Zimmerman
4,327,485	A	5/1982	Rix
4,345,606	A	8/1982	Littleford
4,359,052	A	11/1982	Staub
4,368,736	A	1/1983	Kaster
4,396,139	A	8/1983	Hall et al.
4,407,286	A	10/1983	Noiles et al.
4,411,654	A	10/1983	Boarini et al.
4,412,832	A	11/1983	Kling et al.
4,428,376	A	1/1984	Mericle
4,440,170	A	4/1984	Golden et al.
4,449,531	A	5/1984	Cerwin et al.
4,475,544	A	10/1984	Reis
4,480,356	A	11/1984	Martin
4,485,816	A	12/1984	Krumme
RE31,855	E	3/1985	Osborne
4,505,273	A	3/1985	Braun et al.
4,505,274	A	3/1985	Speelman
4,523,591	A	6/1985	Kaplan et al.
4,523,695	A	6/1985	Braun et al.
4,525,157	A	6/1985	Vailancourt
4,526,174	A	7/1985	Froehlich
4,570,633	A	2/1986	Golden
4,586,503	A	5/1986	Kirsch et al.
4,592,498	A	6/1986	Braun et al.
4,596,559	A	6/1986	Fleischhacker
4,607,638	A	8/1986	Crainich
4,610,251	A	9/1986	Kumar
4,610,252	A	9/1986	Catalano
4,635,634	A	1/1987	Santos
4,644,956	A	2/1987	Morgenstern
4,651,737	A	3/1987	Deniega
4,664,305	A	5/1987	Blake, III et al.
4,665,906	A	5/1987	Jervis
4,687,469	A	8/1987	Osypka
4,693,249	A	9/1987	Schenck et al.
4,719,917	A	1/1988	Barrows et al.
4,724,840	A	2/1988	McVay et al.
4,738,658	A	4/1988	Magro et al.
4,744,364	A	5/1988	Kensey
4,747,407	A	5/1988	Liu et al.
4,759,364	A	7/1988	Boebel
4,771,782	A	9/1988	Millar
4,772,266	A	9/1988	Groshong
4,777,950	A	10/1988	Kees, Jr.
4,789,090	A	12/1988	Blake, III
4,832,688	A	5/1989	Sagae et al.
4,836,204	A	6/1989	Landymore et al.
4,852,568	A	8/1989	Kensey
4,860,746	A	8/1989	Yoon
4,865,026	A	9/1989	Barrett
4,874,122	A	10/1989	Froelich et al.
4,878,915	A	11/1989	Brantigan
4,885,003	A	12/1989	Hillstead
4,886,067	A	12/1989	Palermo
4,887,601	A	12/1989	Richards
4,890,612	A	1/1990	Kensey
4,900,303	A	2/1990	Lemelson
4,902,508	A	2/1990	Badylak et al.
4,917,087	A	4/1990	Walsh et al.
4,917,089	A	4/1990	Sideris
4,929,240	A	5/1990	Kirsch et al.
4,934,364	A	6/1990	Green
4,950,258	A	8/1990	Kawai et al.
4,957,499	A	9/1990	Lipatov et al.
4,961,729	A	10/1990	Vaillancourt
4,967,949	A	11/1990	Sandhaus
4,976,721	A	12/1990	Blasnik et al.
4,983,176	A	1/1991	Cushman et al.
4,997,436	A	3/1991	Oberlander
4,997,439	A	3/1991	Chen
5,002,562	A	3/1991	Oberlander
5,007,921	A	4/1991	Brown
5,011,487	A	4/1991	Shichman
5,015,247	A	5/1991	Michelson
5,021,059	A	6/1991	Kensey et al.
5,026,390	A	6/1991	Brown
5,030,226	A	7/1991	Green et al.
5,032,127	A	7/1991	Frazee et al.
5,035,692	A	7/1991	Lyon et al.
5,041,129	A	8/1991	Hayhurst et al.
5,042,707	A	8/1991	Taheri
5,047,047	A	9/1991	Yoon
5,053,008	A	10/1991	Bajaj
5,059,201	A	10/1991	Asnis
5,061,274	A	10/1991	Kensey
5,061,283	A	10/1991	Silvestrini
5,078,731	A	1/1992	Hayhurst
5,092,941	A	3/1992	Miura
5,100,418	A	3/1992	Yoon et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,100,422	A	3/1992	Berguer et al.
5,108,420	A	4/1992	Marks
5,108,421	A	4/1992	Fowler
5,114,032	A	5/1992	Laidlaw
5,114,065	A	5/1992	Storace
5,116,349	A	5/1992	Aranyi
5,122,122	A	6/1992	Allgood
5,122,156	A	6/1992	Granger et al.
5,131,379	A	7/1992	Sewell, Jr.
5,141,520	A	8/1992	Goble et al.
5,147,381	A	9/1992	Heimerl et al.
5,156,609	A	10/1992	Nakao et al.
5,163,343	A	11/1992	Gish
5,167,634	A	12/1992	Corrigan, Jr. et al.
5,167,643	A	12/1992	Lynn
5,171,249	A	12/1992	Stefanchik et al.
5,171,250	A	12/1992	Yoon
5,171,259	A	12/1992	Inoue
5,176,648	A	1/1993	Holmes et al.
5,192,288	A	3/1993	Thompson et al.
5,192,300	A	3/1993	Fowler
5,192,301	A	3/1993	Kamiya et al.
5,192,302	A	3/1993	Kensey et al.
5,192,602	A	3/1993	Spencer et al.
5,193,533	A	3/1993	Body et al.
5,197,971	A	3/1993	Bonutti
5,207,697	A	5/1993	Carusillo et al.
5,209,756	A	5/1993	Seedhorm et al.
5,217,024	A	6/1993	Dorsey et al.
5,222,974	A	6/1993	Kensey et al.
5,226,908	A	7/1993	Yoon
5,236,435	A	8/1993	Sewell, Jr.
5,242,456	A	9/1993	Nash et al.
5,242,457	A	9/1993	Akopov et al.
5,242,459	A	9/1993	Buelna
5,243,857	A	9/1993	Janota
5,246,156	A	9/1993	Rothfuss et al.
5,246,443	A	9/1993	Mai
5,250,058	A	10/1993	Miller et al.
5,254,105	A	10/1993	Haaga
5,255,679	A	10/1993	Imran
5,269,792	A	12/1993	Kovac et al.
5,275,616	A	1/1994	Fowler
5,281,422	A	1/1994	Badylak et al.
5,282,808	A	2/1994	Kovac et al.
5,282,827	A	2/1994	Kensey et al.
5,284,488	A	2/1994	Sideris
5,289,963	A	3/1994	McGarry et al.
5,290,243	A	3/1994	Chodorow et al.
5,290,310	A	3/1994	Makower et al.
5,292,309	A	3/1994	Van Tassel et al.
5,292,332	A	3/1994	Lee
5,304,183	A	4/1994	Gourlay et al.
5,304,184	A	4/1994	Hathaway et al.
5,304,204	A	4/1994	Bregen
5,306,254	A	4/1994	Nash et al.
5,309,927	A	5/1994	Welch
5,318,542	A	6/1994	Hirsch et al.
5,320,639	A	6/1994	Rudnick
5,322,694	A	6/1994	Sixsmith
5,327,908	A	7/1994	Gerry
5,330,445	A	7/1994	Haaga
5,330,503	A	7/1994	Yoon
5,334,216	A	8/1994	Vidal et al.
5,334,217	A	8/1994	Das
5,335,680	A	8/1994	Moore
5,340,360	A	8/1994	Stefanchik
5,342,393	A	8/1994	Stack
5,344,439	A	9/1994	Otten
5,350,399	A	9/1994	Erlebacher et al.
5,352,229	A	10/1994	Goble et al.
5,354,279	A	10/1994	Hofling
5,364,406	A	11/1994	Sewell, Jr.
5,364,408	A	11/1994	Gordon
5,366,458	A	11/1994	Korthoff et al.
5,366,479	A	11/1994	McGarry et al.
5,383,896	A	1/1995	Gershony et al.
5,383,897	A	1/1995	Wholey
RE34,866	E	2/1995	Kensey et al.
5,392,978	A	2/1995	Valez et al.
5,395,030	A	3/1995	Kuramoto et al.
5,411,520	A	5/1995	Nash et al.
5,413,571	A	5/1995	Katsaros et al.
5,413,584	A	5/1995	Schulze
5,416,584	A	5/1995	Kay
5,417,699	A	5/1995	Klein et al.
5,419,765	A	5/1995	Weldon et al.
5,419,777	A	5/1995	Hofling
5,421,832	A	6/1995	Lefebvre
5,423,857	A	6/1995	Rosenman et al.
5,425,489	A	6/1995	Shichman et al.
5,425,740	A	6/1995	Hutchinson, Jr.
5,431,639	A	7/1995	Shaw
5,431,667	A	7/1995	Thompson et al.
5,433,721	A	7/1995	Hooven et al.
5,437,631	A	8/1995	Janzen
5,439,479	A	8/1995	Shichman et al.
5,443,477	A	8/1995	Marin et al.
5,443,481	A	8/1995	Lee
5,445,167	A	8/1995	Yoon et al.
5,449,359	A	9/1995	Groiso
5,451,235	A	9/1995	Lock et al.
5,456,400	A	10/1995	Shichman et al.
5,462,561	A	10/1995	Voda
5,464,413	A	11/1995	Siska, Jr. et al.
5,464,416	A	11/1995	Steckel
5,466,241	A	11/1995	Leroy et al.
5,470,010	A	11/1995	Rothfuss et al.
5,471,982	A	12/1995	Edwards et al.
5,474,557	A	12/1995	Mai
5,474,569	A	12/1995	Zinreich et al.
5,476,505	A	12/1995	Limon
5,478,352	A	12/1995	Fowler
5,478,353	A	12/1995	Yoon
5,478,354	A	12/1995	Tovey et al.
5,484,420	A	1/1996	Russo
5,486,195	A	1/1996	Myers et al.
5,496,332	A	3/1996	Sierra et al.
5,497,933	A	3/1996	DeFonzo et al.
5,507,744	A	4/1996	Tay et al.
5,507,755	A	4/1996	Gresl et al.
5,510,115	A	4/1996	Breillatt, Jr. et al.
5,522,840	A	6/1996	Krajicek
5,527,322	A	6/1996	Klein et al.
5,536,251	A	7/1996	Evard et al.
5,540,712	A	7/1996	Kleshinski et al.
5,540,716	A	7/1996	Hlavacek
5,544,802	A	8/1996	Crainich
5,545,178	A	8/1996	Kensey et al.
5,547,474	A	8/1996	Kloeckl et al.
5,560,532	A	10/1996	DeFonzo et al.
5,571,120	A	11/1996	Yoon
5,573,784	A	11/1996	Badylak et al.
5,575,771	A	11/1996	Walinsky
5,582,616	A	12/1996	Bolduc et al.
5,584,879	A	12/1996	Reimold et al.
5,591,205	A	1/1997	Fowler
5,593,412	A	1/1997	Martinez et al.
5,601,602	A	2/1997	Fowler
5,609,597	A	3/1997	Lehrer
5,613,974	A	3/1997	Andreas et al.
5,618,291	A	4/1997	Thompson et al.
5,620,452	A	4/1997	Yoon
5,620,461	A	4/1997	Muijs et al.
5,626,614	A	5/1997	Hart
5,634,936	A	6/1997	Linden et al.
5,643,318	A	7/1997	Tsukernik et al.
5,645,565	A	7/1997	Rudd et al.
5,645,566	A	7/1997	Brenneman et al.
5,645,567	A	7/1997	Crainich
5,649,959	A	7/1997	Hannam et al.
D383,539	S	9/1997	Croley
5,674,231	A	10/1997	Green et al.
5,676,689	A	10/1997	Kensey et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,676,974 A		10/1997	Valdes et al.
5,681,280 A		10/1997	Rusk et al.
5,681,334 A		10/1997	Evans et al.
5,683,405 A		11/1997	Yacoubian et al.
5,690,674 A		11/1997	Diaz
5,695,504 A		12/1997	Gifford, III et al.
5,695,505 A		12/1997	Yoon
5,695,524 A		12/1997	Kelley et al.
5,697,943 A		12/1997	Sauer et al.
5,700,273 A		12/1997	Buelna et al.
5,709,224 A		1/1998	Behl et al.
5,715,987 A		2/1998	Kelley et al.
5,716,375 A		2/1998	Fowler
5,720,755 A		2/1998	Dakov
5,725,498 A		3/1998	Janzen et al.
5,725,552 A		3/1998	Kotula et al.
5,725,554 A		3/1998	Simon et al.
5,728,110 A		3/1998	Vidal et al.
5,728,114 A		3/1998	Evans et al.
5,728,116 A		3/1998	Rosenman
5,728,122 A		3/1998	Leschinsky et al.
5,728,132 A		3/1998	Van Tassel et al.
5,728,133 A		3/1998	Kontos
5,732,872 A		3/1998	Bolduc et al.
5,735,873 A		4/1998	MacLean
5,749,826 A		5/1998	Faulkner
5,752,966 A		5/1998	Chang
5,755,726 A		5/1998	Pratt et al.
5,755,727 A		5/1998	Kontos
5,755,778 A		5/1998	Kleshinski
5,766,217 A		6/1998	Christy
5,766,246 A		6/1998	Mulhauser et al.
5,769,870 A		6/1998	Salahieh et al.
5,776,147 A		7/1998	Dolendo
5,779,707 A		7/1998	Bertholet et al.
5,780,807 A		7/1998	Saunders
5,782,844 A		7/1998	Yoon et al.
5,782,860 A		7/1998	Epstein et al.
5,782,861 A		7/1998	Cragg et al.
5,795,958 A		8/1998	Rao et al.
5,797,928 A		8/1998	Kogasaka
5,797,931 A		8/1998	Bito et al.
5,797,933 A		8/1998	Snow et al.
5,797,958 A		8/1998	Yoon
5,797,960 A		8/1998	Stevens et al.
5,810,776 A		9/1998	Bacich et al.
5,810,846 A		9/1998	Virnich et al.
5,810,851 A		9/1998	Yoon
5,817,113 A		10/1998	Gifford, III et al.
5,820,631 A		10/1998	Nobles
5,827,298 A		10/1998	Hart et al.
5,830,125 A		11/1998	Scribner et al.
5,830,217 A		11/1998	Ryan
5,830,221 A		11/1998	Stein et al.
5,833,698 A		11/1998	Hinchliffe et al.
5,843,164 A		12/1998	Frantzen et al.
5,843,167 A		12/1998	Dwyer et al.
5,853,421 A		12/1998	Leschinsky et al.
5,853,422 A		12/1998	Huebsch et al.
5,855,312 A		1/1999	Toledano
5,858,082 A		1/1999	Cruz et al.
5,860,991 A		1/1999	Klein et al.
5,861,003 A		1/1999	Latson et al.
5,861,005 A		1/1999	Kontos
5,861,043 A		1/1999	Carn
5,865,791 A		2/1999	Whayne et al.
5,868,755 A		2/1999	Kanner et al.
5,868,762 A		2/1999	Cragg et al.
5,868,763 A		2/1999	Spence et al.
5,871,474 A		2/1999	Hermann et al.
5,871,501 A		2/1999	Leschinsky et al.
5,871,525 A		2/1999	Edwards et al.
5,873,876 A		2/1999	Christy
5,873,891 A		2/1999	Sohn
5,879,366 A		3/1999	Shaw et al.
5,891,088 A		4/1999	Thompson et al.
5,897,487 A		4/1999	Ouchi
5,902,310 A		5/1999	Foerster et al.
5,904,697 A		5/1999	Gifford, III et al.
5,904,703 A		5/1999	Gilson
5,906,631 A		5/1999	Imran
5,907,893 A		6/1999	Zadno-Azizi et al.
5,908,149 A		6/1999	Welch et al.
5,910,155 A		6/1999	Ratcliff et al.
5,919,207 A		7/1999	Taheri
5,922,009 A		7/1999	Epstein et al.
5,928,231 A		7/1999	Klein et al.
5,928,251 A		7/1999	Aranyi et al.
5,928,260 A		7/1999	Chin et al.
5,935,147 A		8/1999	Kensey et al.
5,938,667 A		8/1999	Peyser et al.
5,941,890 A		8/1999	Voegele et al.
5,947,999 A		9/1999	Groiso
5,948,001 A		9/1999	Larsen
5,951,518 A		9/1999	Licata et al.
5,951,575 A		9/1999	Bolduc et al.
5,951,576 A		9/1999	Wakabayashi
5,951,589 A		9/1999	Epstein et al.
5,954,732 A		9/1999	Hart et al.
5,957,900 A		9/1999	Ouchi
5,957,936 A		9/1999	Yoon et al.
5,957,938 A		9/1999	Zhu et al.
5,957,940 A		9/1999	Tanner et al.
5,964,782 A		10/1999	Lafontaine et al.
5,972,023 A		10/1999	Tanner et al.
5,972,034 A		10/1999	Hofmann et al.
5,976,161 A		11/1999	Kirsch et al.
5,976,174 A		11/1999	Ruiz
5,984,934 A		11/1999	Ashby et al.
5,984,948 A		11/1999	Hasson
5,984,949 A		11/1999	Levin
5,993,468 A		11/1999	Rygaard
5,993,476 A		11/1999	Groiso
6,001,110 A		12/1999	Adams
6,004,341 A		12/1999	Zhu et al.
6,007,563 A		12/1999	Nash et al.
6,007,574 A		12/1999	Pulnev et al.
6,010,517 A		1/2000	Baccaro
6,013,084 A		1/2000	Ken et al.
6,015,815 A		1/2000	Mollison
6,019,779 A		2/2000	Thorud et al.
6,022,372 A		2/2000	Kontos
6,024,750 A		2/2000	Mastri et al.
6,024,756 A		2/2000	Huebsch et al.
6,030,364 A		2/2000	Durgin et al.
6,030,413 A		2/2000	Lazarus
6,033,427 A		3/2000	Lee
6,036,703 A		3/2000	Evans et al.
6,036,720 A		3/2000	Abrams et al.
6,045,570 A		4/2000	Epstein et al.
6,048,358 A		4/2000	Barak
6,056,768 A		5/2000	Cates et al.
6,056,769 A		5/2000	Epstein et al.
6,056,770 A		5/2000	Epstein et al.
6,059,800 A		5/2000	Hart et al.
6,059,825 A		5/2000	Hobbs et al.
6,063,085 A		5/2000	Tay et al.
6,063,114 A		5/2000	Nash et al.
6,071,300 A		6/2000	Brenneman et al.
6,074,395 A		6/2000	Trott et al.
6,077,281 A		6/2000	Das
6,077,291 A		6/2000	Das
6,080,182 A		6/2000	Shaw et al.
6,080,183 A		6/2000	Tsugita et al.
6,090,130 A		7/2000	Nash et al.
6,102,271 A		8/2000	Longo et al.
6,110,184 A		8/2000	Weadock
6,113,610 A		9/2000	Poncet
6,113,611 A		9/2000	Allen et al.
6,113,612 A		9/2000	Swanson et al.
6,117,125 A		9/2000	Rothbarth et al.
6,117,144 A	*	9/2000	Nobles A61B 17/0057 606/139
6,117,148 A		9/2000	Ravo

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,117,157	A	9/2000	Tekulve
6,117,159	A	9/2000	Huebsch et al.
6,120,524	A	9/2000	Taheri
6,126,675	A	10/2000	Schervinsky et al.
6,136,010	A	10/2000	Modesitt et al.
6,146,385	A	11/2000	Torrie et al.
6,149,660	A	11/2000	Laufer et al.
6,149,667	A	11/2000	Hovland et al.
6,152,144	A	11/2000	Lesh et al.
6,152,936	A	11/2000	Christy et al.
6,152,937	A	11/2000	Peterson et al.
6,165,204	A	12/2000	Levinson et al.
6,171,277	B1	1/2001	Ponzi
6,171,329	B1	1/2001	Shaw et al.
6,174,322	B1	1/2001	Schneidt
6,179,849	B1	1/2001	Yencho et al.
6,179,860	B1	1/2001	Fulton, III et al.
6,183,775	B1	2/2001	Ventouras
6,193,708	B1	2/2001	Ken et al.
6,193,734	B1	2/2001	Bolduc et al.
6,197,042	B1	3/2001	Ginn et al.
6,198,974	B1	3/2001	Webster, Jr.
6,200,329	B1	3/2001	Fung et al.
6,200,330	B1	3/2001	Benderev et al.
6,206,895	B1	3/2001	Levinson
6,206,913	B1	3/2001	Yencho et al.
6,206,931	B1	3/2001	Cook et al.
6,210,407	B1	4/2001	Webster
6,210,418	B1	4/2001	Storz et al.
6,217,554	B1	4/2001	Green
6,220,248	B1	4/2001	Voegele et al.
6,221,102	B1	4/2001	Baker et al.
6,231,561	B1	5/2001	Frazier et al.
6,238,705	B1	5/2001	Liu et al.
6,241,740	B1	6/2001	Davis et al.
6,245,079	B1	6/2001	Nobles et al.
6,248,124	B1	6/2001	Pedros et al.
6,254,617	B1	7/2001	Spence et al.
6,254,642	B1	7/2001	Taylor
6,258,115	B1	7/2001	Dubrul
6,261,309	B1	7/2001	Urbanski
6,267,773	B1	7/2001	Gadberry et al.
6,273,903	B1	8/2001	Wilk
6,277,140	B2	8/2001	Ginn et al.
6,280,460	B1	8/2001	Bolduc et al.
6,287,322	B1	9/2001	Zhu et al.
6,287,335	B1	9/2001	Drasler et al.
6,290,674	B1	9/2001	Roue et al.
6,296,657	B1	10/2001	Brucker
6,302,870	B1	10/2001	Jacobsen et al.
6,302,898	B1	10/2001	Edwards et al.
6,305,891	B1	10/2001	Burlingame
6,309,416	B1	10/2001	Swanson et al.
6,319,258	B1	11/2001	McAllen, III et al.
6,322,580	B1	11/2001	Kanner
6,328,727	B1	12/2001	Frazier et al.
6,329,386	B1	12/2001	Mollison
6,334,865	B1	1/2002	Redmond et al.
6,348,064	B1	2/2002	Kanner
6,355,052	B1	3/2002	Neuss et al.
6,358,258	B1	3/2002	Arcia et al.
6,375,671	B1	4/2002	Kobayashi et al.
D457,958	S	5/2002	Dycus
6,383,208	B1	5/2002	Sancoff et al.
6,391,048	B1	5/2002	Ginn et al.
6,395,015	B1	5/2002	Borst et al.
6,398,752	B1	6/2002	Sweezer, Jr. et al.
6,402,765	B1	6/2002	Monassevitch et al.
6,409,739	B1	6/2002	Nobles et al.
6,419,669	B1	7/2002	Frazier et al.
6,421,899	B1	7/2002	Zitnay
6,423,054	B1	7/2002	Ouchi
6,425,911	B1	7/2002	Akerfeldt et al.
6,428,472	B1	8/2002	Haas
6,428,548	B1	8/2002	Durgin et al.
6,443,158	B1	9/2002	Lafontaine et al.
6,443,963	B1	9/2002	Baldwin et al.
6,447,540	B1	9/2002	Fontaine et al.
6,450,391	B1	9/2002	Kayan et al.
6,455,053	B1	9/2002	Okada et al.
6,458,130	B1	10/2002	Frazier et al.
6,461,364	B1	10/2002	Ginn et al.
6,482,224	B1	11/2002	Michler et al.
6,488,692	B1	12/2002	Spence et al.
6,494,848	B1	12/2002	Sommercorn et al.
6,500,115	B2	12/2002	Krattiger et al.
6,506,210	B1	1/2003	Kanner
6,508,828	B1	1/2003	Akerfeldt et al.
6,514,280	B1	2/2003	Gilson
6,517,555	B1	2/2003	Caro
6,517,569	B2	2/2003	Mikus et al.
6,527,737	B2	3/2003	Kaneshige
6,533,762	B2	3/2003	Kanner et al.
6,533,812	B2	3/2003	Swanson et al.
6,537,288	B2	3/2003	Vargas et al.
6,544,230	B1	4/2003	Flaherty et al.
6,547,806	B1	4/2003	Ding
6,551,319	B2	4/2003	Lieberman
6,558,349	B1	5/2003	Kirkman
6,569,173	B1	5/2003	Blatter et al.
6,569,185	B2	5/2003	Ungs
6,572,629	B2	6/2003	Kalloo et al.
6,582,452	B2	6/2003	Coleman et al.
6,582,482	B2	6/2003	Gillman et al.
6,596,012	B2	7/2003	Akerfeldt et al.
6,596,013	B2	7/2003	Yang et al.
6,599,303	B1	7/2003	Peterson et al.
6,599,311	B1	7/2003	Biggs et al.
6,602,263	B1	8/2003	Swanson et al.
6,610,072	B1	8/2003	Christy et al.
6,613,059	B2	9/2003	Schaller et al.
6,616,686	B2	9/2003	Coleman et al.
6,620,165	B2	9/2003	Wellisz
6,623,509	B2	9/2003	Ginn
6,623,510	B2	9/2003	Carley et al.
6,626,918	B1	9/2003	Ginn et al.
6,626,919	B1	9/2003	Swanstrom
6,626,920	B2	9/2003	Whayne
6,626,930	B1	9/2003	Allen et al.
6,632,197	B2	10/2003	Lyon
6,632,238	B2	10/2003	Ginn et al.
6,634,537	B2	10/2003	Chen
6,645,205	B2	11/2003	Ginn
6,645,225	B1	11/2003	Atkinson
6,652,538	B2	11/2003	Kayan et al.
6,652,556	B1	11/2003	VanTassel et al.
6,663,633	B1	12/2003	Pierson, III
6,663,655	B2	12/2003	Ginn et al.
6,669,714	B2	12/2003	Coleman et al.
6,673,083	B1	1/2004	Kayan et al.
6,676,665	B2	1/2004	Foley et al.
6,676,671	B2	1/2004	Robertson et al.
6,676,685	B2	1/2004	Pedros et al.
6,679,904	B2	1/2004	Gleeson et al.
6,685,707	B2	2/2004	Roman et al.
6,689,147	B1	2/2004	Koster, Jr.
6,695,867	B2	2/2004	Ginn et al.
6,699,256	B1	3/2004	Logan et al.
6,702,826	B2	3/2004	Liddicoat et al.
6,712,836	B1	3/2004	Berg et al.
6,712,837	B2	3/2004	Akerfeldt et al.
6,719,777	B2	4/2004	Ginn et al.
6,726,704	B1	4/2004	Loshakove et al.
6,743,195	B2	6/2004	Zucker
6,743,243	B1	6/2004	Roy et al.
6,743,259	B2	6/2004	Ginn
6,746,472	B2	6/2004	Frazier et al.
6,749,621	B2	6/2004	Pantages et al.
6,749,622	B2	6/2004	McGuckin et al.
6,752,813	B2	6/2004	Goldfarb et al.
6,755,842	B2	6/2004	Kanner et al.
6,758,855	B2	7/2004	Fulton, III et al.
6,767,356	B2	7/2004	Kanner et al.
6,776,784	B2	8/2004	Ginn

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,780,197 B2	8/2004	Roe et al.	
6,786,915 B2	9/2004	Akerfeldt et al.	
6,790,218 B2	9/2004	Jayaraman	
6,790,220 B2	9/2004	Morris et al.	
6,837,893 B2	1/2005	Miller	
6,837,906 B2	1/2005	Ginn	
6,846,319 B2	1/2005	Ginn et al.	
6,860,895 B1	3/2005	Akerfeldt et al.	
6,890,343 B2	5/2005	Ginn et al.	
6,896,687 B2	5/2005	Dakov	
6,896,692 B2	5/2005	Ginn et al.	
6,913,607 B2	7/2005	Ainsworth et al.	
6,926,723 B1	8/2005	Mulhauser et al.	
6,926,731 B2	8/2005	Coleman et al.	
6,929,634 B2	8/2005	Dorros et al.	
6,942,641 B2	9/2005	Seddon	
6,942,674 B2	9/2005	Belef et al.	
6,942,691 B1	9/2005	Chuter	
6,964,668 B2	11/2005	Modesitt et al.	
6,969,391 B1	11/2005	Gazzani	
6,969,397 B2	11/2005	Ginn	
6,989,003 B2	1/2006	Wing et al.	
6,989,016 B2	1/2006	Tallarida et al.	
7,001,398 B2	2/2006	Carley et al.	
7,001,400 B1	2/2006	Modesitt et al.	
7,008,435 B2	3/2006	Cummins	
7,008,439 B1	3/2006	Janzen et al.	
7,025,776 B1	4/2006	Houser et al.	
7,033,379 B2	4/2006	Peterson	
7,060,084 B1	6/2006	Loshakove et al.	
7,063,711 B1	6/2006	Loshakove et al.	
7,074,232 B2	7/2006	Kanner et al.	
7,076,305 B2	7/2006	Imran et al.	
7,083,635 B2	8/2006	Ginn	
7,087,064 B1	8/2006	Hyde	
7,087,088 B2	8/2006	Berg et al.	
7,108,709 B2	9/2006	Cummins	
7,111,768 B2	9/2006	Cummins et al.	
7,112,225 B2	9/2006	Ginn	
7,144,411 B2	12/2006	Ginn et al.	
7,163,551 B2	1/2007	Anthony et al.	
7,169,158 B2	1/2007	Sniffin et al.	
7,169,164 B2	1/2007	Borillo et al.	
7,211,101 B2	5/2007	Carley et al.	
7,220,268 B2	5/2007	Blatter	
7,229,452 B2	6/2007	Kayan	
7,261,716 B2	8/2007	Strobel et al.	
7,306,614 B2	12/2007	Weller et al.	
7,311,720 B2	12/2007	Mueller et al.	
7,316,704 B2	1/2008	Bagaoisan et al.	
7,316,706 B2	1/2008	Bloom et al.	
7,322,995 B2	1/2008	Buckman et al.	
7,326,230 B2	2/2008	Ravikumar	
7,331,979 B2	2/2008	Khosravi et al.	
7,335,220 B2	2/2008	Khosravi et al.	
D566,272 S	4/2008	Walburg et al.	
7,361,178 B2	4/2008	Hearn et al.	
7,361,183 B2	4/2008	Ginn	
7,361,185 B2	4/2008	O'Malley et al.	
7,393,363 B2	7/2008	Ginn	
7,396,359 B1	7/2008	Derowe et al.	
7,431,729 B2	10/2008	Chanduszko	
7,445,596 B2	11/2008	Kucklick et al.	
7,465,286 B2	12/2008	Patterson et al.	
7,533,790 B1	5/2009	Knodel et al.	
7,556,632 B2	7/2009	Zadno	
7,582,103 B2	9/2009	Young et al.	
7,582,104 B2	9/2009	Corcoran et al.	
7,597,706 B2	10/2009	Kanner et al.	
7,618,427 B2	11/2009	Ortiz et al.	
7,622,628 B2	11/2009	Bergin et al.	
D611,144 S	3/2010	Reynolds	
7,678,135 B2	3/2010	Maahs et al.	
7,780,696 B2	8/2010	Daniel et al.	
7,806,904 B2	10/2010	Carley et al.	
7,819,895 B2	10/2010	Ginn et al.	
7,824,419 B2 *	11/2010	Boraiah	A61B 17/0057 606/139
7,841,502 B2	11/2010	Walberg et al.	
7,842,068 B2	11/2010	Ginn	
7,850,709 B2	12/2010	Cummins et al.	
7,850,710 B2	12/2010	Huss	
7,850,797 B2	12/2010	Carley et al.	
7,854,810 B2	12/2010	Carley et al.	
7,857,828 B2	12/2010	Jabba et al.	
7,867,249 B2	1/2011	Palermo et al.	
7,875,054 B2	1/2011	LaFontaine	
7,879,071 B2	2/2011	Carley et al.	
7,887,555 B2	2/2011	Carley et al.	
7,887,563 B2	2/2011	Cummins	
7,901,428 B2	3/2011	Ginn et al.	
7,905,900 B2	3/2011	Palermo et al.	
7,918,873 B2	4/2011	Cummins	
7,931,669 B2	4/2011	Ginn et al.	
7,931,671 B2	4/2011	Tenerz	
7,967,842 B2	6/2011	Bakos	
8,007,512 B2	8/2011	Ginn et al.	
8,083,768 B2	12/2011	Ginn et al.	
8,103,327 B2	1/2012	Harlev et al.	
8,105,352 B2	1/2012	Egnelöv	
8,128,644 B2	3/2012	Carley et al.	
8,172,749 B2	5/2012	Melsheimer	
8,182,497 B2	5/2012	Carley et al.	
8,192,459 B2	6/2012	Cummins et al.	
8,202,283 B2	6/2012	Carley et al.	
8,202,293 B2	6/2012	Ellingwood et al.	
8,202,294 B2	6/2012	Jabba et al.	
8,216,260 B2	7/2012	Lam et al.	
8,226,681 B2	7/2012	Clark et al.	
8,236,026 B2	8/2012	Carley et al.	
8,257,390 B2	9/2012	Carley et al.	
8,303,624 B2	11/2012	Fortson	
8,313,497 B2	11/2012	Walberg et al.	
8,323,312 B2	12/2012	Clark	
8,398,656 B2	3/2013	Palermo et al.	
8,398,676 B2	3/2013	Roorda et al.	
8,403,929 B2	3/2013	Weisshaupt et al.	
8,409,228 B2	4/2013	Blatter et al.	
8,469,995 B2	6/2013	Cummins et al.	
8,480,687 B2	7/2013	Ducharme et al.	
8,486,092 B2	7/2013	Carley et al.	
8,486,108 B2	7/2013	Carley et al.	
8,518,057 B2	8/2013	Walberg et al.	
8,529,587 B2	9/2013	Ellingwood et al.	
8,556,930 B2	10/2013	Ellingwood	
8,556,932 B2	10/2013	Ziobro	
8,562,630 B2	10/2013	Campbell	
8,579,932 B2	11/2013	Pantages	
8,585,836 B2	11/2013	Carley et al.	
8,590,760 B2	11/2013	Cummins et al.	
8,597,325 B2	12/2013	Ginn	
8,603,116 B2	12/2013	Roorda	
8,603,136 B2	12/2013	Ginn	
8,617,184 B2	12/2013	Oepen	
8,657,852 B2	2/2014	Roorda et al.	
8,672,953 B2	3/2014	Reyes et al.	
8,690,910 B2	4/2014	Carley et al.	
8,728,119 B2	5/2014	Cummins	
8,758,396 B2	6/2014	Ginn et al.	
8,758,398 B2	6/2014	Carley	
8,758,399 B2	6/2014	Fortson et al.	
8,758,400 B2	6/2014	Ginn et al.	
8,784,447 B2	7/2014	Coleman et al.	
8,808,310 B2	8/2014	Jones et al.	
8,820,602 B2	9/2014	Walberg et al.	
8,821,534 B2	9/2014	Voss	
8,834,494 B2 *	9/2014	Schorr	A61B 17/0469 606/139
8,858,594 B2	10/2014	Clark	
8,893,947 B2	11/2014	Reynolds et al.	
8,905,937 B2	12/2014	Ellingwood et al.	
8,926,633 B2	1/2015	Carly	
8,926,656 B2	1/2015	Palermo et al.	
8,956,388 B2	2/2015	Ginn et al.	

(56) **References Cited**

U.S. PATENT DOCUMENTS

8,992,549	B2 *	3/2015	Bennett, III	A61B 17/0057 606/144
9,050,068	B2	6/2015	Walberg et al.	
9,050,087	B2	6/2015	Ginn et al.	
9,060,769	B2	6/2015	Coleman et al.	
9,089,311	B2	7/2015	Fortson et al.	
9,089,674	B2	7/2015	Ginn et al.	
9,173,644	B2	11/2015	Voss	
2001/0007077	A1	7/2001	Ginn et al.	
2001/0021855	A1	9/2001	Levinson	
2001/0031972	A1	10/2001	Robertson et al.	
2001/0031973	A1 *	10/2001	Nobles	A61B 17/0057 606/144
2001/0044639	A1	11/2001	Levinson	
2001/0046518	A1	11/2001	Sawhney	
2001/0047180	A1	11/2001	Grudem et al.	
2002/0022822	A1	2/2002	Cragg et al.	
2002/0026215	A1	2/2002	Redmond et al.	
2002/0026216	A1	2/2002	Grimes	
2002/0029050	A1	3/2002	Gifford, III et al.	
2002/0038127	A1	3/2002	Blatter et al.	
2002/0042622	A1	4/2002	Vargas et al.	
2002/0049427	A1	4/2002	Wiener et al.	
2002/0049453	A1 *	4/2002	Nobles	A61B 17/0057 606/139
2002/0058960	A1	5/2002	Hudson et al.	
2002/0062104	A1	5/2002	Ashby et al.	
2002/0077656	A1	6/2002	Ginn et al.	
2002/0077657	A1	6/2002	Ginn et al.	
2002/0077658	A1	6/2002	Ginn	
2002/0082641	A1	6/2002	Ginn et al.	
2002/0095164	A1	7/2002	Andreas et al.	
2002/0095181	A1	7/2002	Beyar	
2002/0099389	A1	7/2002	Michler et al.	
2002/0106409	A1	8/2002	Sawhney et al.	
2002/0107542	A1	8/2002	Kanner et al.	
2002/0151921	A1	10/2002	Kanner et al.	
2002/0151963	A1	10/2002	Brown et al.	
2002/0169475	A1	11/2002	Gainor et al.	
2002/0183786	A1	12/2002	Girton	
2002/0183787	A1	12/2002	Wahr et al.	
2002/0188170	A1	12/2002	Santamore et al.	
2002/0198562	A1	12/2002	Akerfeldt et al.	
2002/0198589	A1	12/2002	Leong	
2003/0004543	A1	1/2003	Gleeson et al.	
2003/0009180	A1	1/2003	Hinchliffe et al.	
2003/0018358	A1	1/2003	Saadat	
2003/0023248	A1	1/2003	Parodi	
2003/0032981	A1	2/2003	Kanner et al.	
2003/0033006	A1	2/2003	Phillips et al.	
2003/0045893	A1	3/2003	Ginn	
2003/0055455	A1	3/2003	Yang et al.	
2003/0060846	A1	3/2003	Egnelov et al.	
2003/0065358	A1	4/2003	Frecker et al.	
2003/0078465	A1	4/2003	Pai et al.	
2003/0083679	A1	5/2003	Grudem et al.	
2003/0093096	A1	5/2003	McGuckin et al.	
2003/0093108	A1	5/2003	Avellanet et al.	
2003/0097140	A1	5/2003	Kanner	
2003/0109890	A1	6/2003	Kanner et al.	
2003/0125766	A1	7/2003	Ding	
2003/0139819	A1	7/2003	Beer et al.	
2003/0144695	A1	7/2003	McGuckin, Jr. et al.	
2003/0158578	A1	8/2003	Pantages et al.	
2003/0167063	A1	9/2003	Kerr	
2003/0195504	A1	10/2003	Tallarida et al.	
2003/0208211	A1	11/2003	Kortenbach	
2004/0002763	A1	1/2004	Phillips et al.	
2004/0009205	A1	1/2004	Sawhney	
2004/0044350	A1	3/2004	Martin et al.	
2004/0049224	A1	3/2004	Buehlmann et al.	
2004/0059376	A1	3/2004	Breuniger	
2004/0068273	A1 *	4/2004	Fariss	A61B 17/0057 606/144
2004/0078053	A1	4/2004	Berg et al.	
2004/0082906	A1	4/2004	Tallarida et al.	
2004/0087985	A1	5/2004	Loshakove et al.	
2004/0092962	A1	5/2004	Thornton et al.	
2004/0092964	A1	5/2004	Modesitt et al.	
2004/0092968	A1	5/2004	Caro et al.	
2004/0092973	A1	5/2004	Chanduszko et al.	
2004/0093024	A1	5/2004	Lousararian et al.	
2004/0093027	A1	5/2004	Fabisiak et al.	
2004/0097978	A1	5/2004	Modesitt et al.	
2004/0106980	A1	6/2004	Solovay et al.	
2004/0127940	A1	7/2004	Ginn et al.	
2004/0143290	A1	7/2004	Brightbill	
2004/0143291	A1	7/2004	Corcoran et al.	
2004/0147957	A1	7/2004	Pierson, III	
2004/0158127	A1	8/2004	Okada	
2004/0158287	A1	8/2004	Cragg et al.	
2004/0158309	A1	8/2004	Wachter et al.	
2004/0167511	A1	8/2004	Buehlmann et al.	
2004/0191277	A1	9/2004	Sawhney et al.	
2004/0215232	A1	10/2004	Belhe et al.	
2004/0243216	A1	12/2004	Gregorich	
2004/0249412	A1	12/2004	Snow et al.	
2004/0254591	A1	12/2004	Kanner et al.	
2004/0267193	A1	12/2004	Bagaoisan et al.	
2004/0267308	A1	12/2004	Bagaoisan et al.	
2004/0267312	A1	12/2004	Kanner et al.	
2005/0038460	A1	2/2005	Jayaraman	
2005/0038500	A1	2/2005	Boylan et al.	
2005/0059982	A1	3/2005	Zung et al.	
2005/0075654	A1	4/2005	Kelleher	
2005/0075665	A1	4/2005	Brenzel et al.	
2005/0085851	A1	4/2005	Fiehler et al.	
2005/0085854	A1	4/2005	Ginn	
2005/0085855	A1	4/2005	Forsberg	
2005/0090859	A1	4/2005	Ravlkumar	
2005/0119695	A1	6/2005	Carley et al.	
2005/0121042	A1	6/2005	Belhe et al.	
2005/0148818	A1	7/2005	Mesallum	
2005/0149117	A1	7/2005	Khosravi et al.	
2005/0152949	A1	7/2005	Hotchkiss et al.	
2005/0154401	A1	7/2005	Weldon et al.	
2005/0165357	A1	7/2005	McGuckin et al.	
2005/0169974	A1	8/2005	Tenerez et al.	
2005/0177189	A1	8/2005	Ginn et al.	
2005/0187564	A1	8/2005	Jayaraman	
2005/0203552	A1	9/2005	Laufer et al.	
2005/0222614	A1	10/2005	Ginn et al.	
2005/0228443	A1	10/2005	Yassinzadeh	
2005/0245876	A1	11/2005	Khosravi et al.	
2005/0256532	A1	11/2005	Nayak et al.	
2005/0267524	A1	12/2005	Chanduszko	
2005/0273136	A1	12/2005	Belef et al.	
2005/0273137	A1	12/2005	Ginn	
2005/0283188	A1	12/2005	Loshakove et al.	
2006/0030867	A1	2/2006	Zadno	
2006/0034930	A1	2/2006	Khosravi et al.	
2006/0047313	A1	3/2006	Khanna et al.	
2006/0064115	A1	3/2006	Allen et al.	
2006/0100664	A1	5/2006	Pai et al.	
2006/0142784	A1	6/2006	Kontos	
2006/0190014	A1	8/2006	Ginn et al.	
2006/0190036	A1	8/2006	Wendel et al.	
2006/0190037	A1	8/2006	Ginn et al.	
2006/0195123	A1	8/2006	Ginn et al.	
2006/0195125	A1	8/2006	Sakakine et al.	
2006/0206146	A1	9/2006	Tenerz	
2006/0217744	A1	9/2006	Bender et al.	
2006/0229553	A1	10/2006	Hammack et al.	
2006/0253037	A1	11/2006	Ginn et al.	
2006/0253072	A1	11/2006	Pai et al.	
2006/0281968	A1	12/2006	Duran et al.	
2006/0287673	A1	12/2006	Brett et al.	
2006/0287674	A1	12/2006	Ginn et al.	
2006/0293698	A1	12/2006	Douk	
2007/0005093	A1	1/2007	Cox	
2007/0010851	A1	1/2007	Chanduszko et al.	
2007/0027476	A1	2/2007	Harris et al.	
2007/0027525	A1	2/2007	Ben-Muvhar	
2007/0049968	A1	3/2007	Sibbitt, Jr. et al.	

(56) **References Cited**

U.S. PATENT DOCUMENTS

2007/0049970	A1	3/2007	Belef et al.
2007/0060858	A1	3/2007	Sogard et al.
2007/0060895	A1	3/2007	Sibbitt, Jr. et al.
2007/0060950	A1	3/2007	Khosravi et al.
2007/0073337	A1	3/2007	Abbott et al.
2007/0078302	A1	4/2007	Ortiz et al.
2007/0083230	A1	4/2007	Javois
2007/0083231	A1	4/2007	Lee
2007/0093869	A1	4/2007	Bloom et al.
2007/0112304	A1	5/2007	Voss
2007/0112365	A1	5/2007	Hilal et al.
2007/0112385	A1	5/2007	Conlon
2007/0123816	A1	5/2007	Zhu et al.
2007/0123817	A1	5/2007	Khosravi et al.
2007/0149996	A1	6/2007	Coughlin
2007/0167981	A1	7/2007	Opolski et al.
2007/0172430	A1	7/2007	Brito et al.
2007/0179527	A1	8/2007	Eskuri et al.
2007/0185529	A1	8/2007	Coleman et al.
2007/0185530	A1	8/2007	Chin-Chen et al.
2007/0203507	A1	8/2007	McLaughlin et al.
2007/0225755	A1	9/2007	Preinitz et al.
2007/0225756	A1	9/2007	Preinitz et al.
2007/0225757	A1	9/2007	Preinitz et al.
2007/0225758	A1	9/2007	Preinitz et al.
2007/0239209	A1	10/2007	Fallman
2007/0265658	A1	11/2007	Nelson et al.
2007/0275036	A1	11/2007	Green, III et al.
2007/0276488	A1	11/2007	Wachter et al.
2007/0282373	A1	12/2007	Ashby et al.
2008/0009794	A1	1/2008	Bagaoisan et al.
2008/0033459	A1*	2/2008	Shafi A61B 17/0057 606/144
2008/0045979	A1	2/2008	Ma
2008/0058839	A1	3/2008	Nobles et al.
2008/0065151	A1	3/2008	Ginn
2008/0082123	A1	4/2008	Forsberg et al.
2008/0086075	A1	4/2008	Isik et al.
2008/0091235	A1	4/2008	Sirota
2008/0093414	A1	4/2008	Bender et al.
2008/0097509	A1	4/2008	Beyar et al.
2008/0114378	A1	5/2008	Matsushita
2008/0114395	A1	5/2008	Mathisen et al.
2008/0177288	A1	7/2008	Carlson
2008/0208225	A1	8/2008	Seibold et al.
2008/0215089	A1	9/2008	Williams et al.
2008/0215090	A1	9/2008	Gonzales et al.
2008/0243148	A1	10/2008	Mikkaichi et al.
2008/0243182	A1	10/2008	Bates et al.
2008/0249504	A1	10/2008	Lattouf et al.
2008/0269801	A1	10/2008	Coleman et al.
2008/0269802	A1	10/2008	Coleman et al.
2008/0287988	A1	11/2008	Smith et al.
2008/0294001	A1	11/2008	Surti
2008/0300628	A1	12/2008	Ellingwood
2008/0312667	A1	12/2008	Drasler et al.
2008/0312686	A1	12/2008	Ellingwood
2008/0312740	A1	12/2008	Wachter et al.
2009/0054912	A1	2/2009	Heanue et al.
2009/0062846	A1	3/2009	Ken
2009/0112306	A1	4/2009	Bonsignore et al.
2009/0132031	A1	5/2009	Cook et al.
2009/0137900	A1	5/2009	Bonner et al.
2009/0157101	A1	6/2009	Reyes et al.
2009/0171388	A1	7/2009	Dave et al.
2009/0187215	A1	7/2009	Mackiewicz et al.
2009/0216267	A1	8/2009	Willard et al.
2009/0221960	A1	9/2009	Albrecht et al.
2009/0227938	A1	9/2009	Fasching et al.
2009/0230168	A1	9/2009	Coleman et al.
2009/0254119	A1	10/2009	Sibbitt, Jr. et al.
2009/0259233	A1	10/2009	Bogart et al.
2009/0287244	A1	11/2009	Kokish
2009/0299133	A1	12/2009	Gifford, III et al.
2009/0312789	A1	12/2009	Kassab et al.
2010/0022821	A1	1/2010	Dubi et al.
2010/0042118	A1	2/2010	Garrison et al.
2010/0042144	A1	2/2010	Bennett
2010/0114156	A1	5/2010	Mehl
2010/0130965	A1	5/2010	Sibbitt, Jr. et al.
2010/0179567	A1*	7/2010	Voss A61B 17/0057 606/139
2010/0179572	A1	7/2010	Voss et al.
2010/0179589	A1	7/2010	Roorda et al.
2010/0185216	A1	7/2010	Garrison et al.
2010/0185234	A1	7/2010	Fortson et al.
2010/0249828	A1	9/2010	Mavani et al.
2011/0054492	A1	3/2011	Clark
2011/0082495	A1	4/2011	Ruiz
2011/0137340	A1	6/2011	Cummins
2011/0178548	A1	7/2011	Tenerz
2011/0218568	A1	9/2011	Voss
2011/0270282	A1	11/2011	Lemke
2011/0288563	A1	11/2011	Gianotti et al.
2011/0313452	A1	12/2011	Carley et al.
2012/0101520	A1	4/2012	Ginn et al.
2012/0245623	A1	9/2012	Kariniemi et al.
2013/0053792	A1	2/2013	Fischell et al.
2013/0138144	A1	5/2013	Yibarren
2013/0190778	A1	7/2013	Palermo
2013/0310853	A1	11/2013	Zaugg et al.
2013/0338708	A1	12/2013	Cummins et al.
2014/0005692	A1	1/2014	Ellingwood et al.
2014/0018850	A1	1/2014	Ellingwood
2014/0142624	A1	5/2014	Pantages et al.
2014/0222068	A1	8/2014	Carley et al.
2014/0222069	A1	8/2014	Carley et al.
2014/0309686	A1	10/2014	Ginn et al.
2014/0364900	A1	12/2014	Fortson et al.
2014/0364903	A1	12/2014	Roorda et al.
2015/0073471	A1	3/2015	Clark
2015/0190071	A1	7/2015	Ellingwood et al.
2015/0265279	A1	9/2015	Walberg et al.

FOREIGN PATENT DOCUMENTS

DE	197 11 288	10/1998
DE	29723736 U1	4/1999
DE	19859952	2/2000
DE	102006056283	6/2008
EP	0 386 361	9/1990
EP	0 534 696	3/1993
EP	0 621 032	10/1994
EP	0 756 851	2/1997
EP	0 774 237	5/1997
EP	0 858 776	8/1998
EP	0 941 697	9/1999
EP	1 867 287	12/2007
FR	2 443 238	7/1980
FR	2 715 290	7/1995
FR	2 722 975	2/1996
FR	2 768 324	3/1999
GB	1 358 466	7/1974
GB	2 075 144	11/1981
GB	2 397 240	7/2004
IE	S2000/0722	10/2001
IE	S2000/0724	10/2001
IE	S2001/0547	7/2002
IE	S2001/0815	7/2002
IE	S2001/0748	8/2002
IE	S2001/0749	8/2002
IE	S2002/0452	12/2002
IE	S2002/0664	2/2003
IE	S2002/0665	2/2003
IE	S2002/0451	7/2003
IE	S2002/0552	7/2003
IE	S2003/0424	12/2003
IE	S2003/0490	1/2004
IE	S2004/0368	11/2005
IE	S2005/0342	11/2005
JP	58-181006	12/1983
JP	12 74750	11/1989
JP	11500642	8/1997
JP	2000102546	4/2000

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

NL	9302140	7/1995
PL	171425	4/1997
RU	2086192	8/1997
SU	495067	12/1975
SU	912155	3/1982
SU	1243708	7/1986
SU	1324650	7/1987
SU	1405828	6/1988
SU	1456109	2/1989
SU	1560133	4/1990
WO	WO 96/24291	8/1996
WO	WO 97/00046	1/1997
WO	WO 97/07741	3/1997
WO	WO 97/20505	6/1997
WO	WO 97/27897	8/1997
WO	WO 98/06346	2/1998
WO	WO 98/06448	2/1998
WO	WO 98/16161	4/1998
WO	WO 98/17179	4/1998
WO	WO 98/18389	5/1998
WO	WO 98/24374	6/1998
WO	WO 98/25508	6/1998
WO	WO 98/58591	12/1998
WO	WO 99/21491	5/1999
WO	WO 99/40849	8/1999
WO	WO 99/60941	12/1999
WO	WO 99/62408	12/1999
WO	WO 99/62415	12/1999
WO	WO 00/06029	2/2000
WO	WO 00/07505	2/2000
WO	WO 00/07640	2/2000
WO	WO 00/27311	5/2000
WO	WO 00/27313	5/2000
WO	WO 00/56223	9/2000
WO	WO 00/56227	9/2000
WO	WO 00/56228	9/2000
WO	WO 00/71032	11/2000
WO	WO 01/21058	3/2001
WO	WO 01/35832	5/2001
WO	WO 01/47594	7/2001
WO	WO 01/49186	7/2001
WO	WO 01/91628	12/2001
WO	WO 02/19915	3/2002
WO	WO 02/19920	3/2002
WO	WO 02/19922	3/2002
WO	WO 02/19924	3/2002
WO	WO 02/28286	4/2002
WO	WO 02/38055	5/2002
WO	WO 02/45593	6/2002
WO	WO 02/45594	6/2002
WO	WO 02/062234	8/2002
WO	WO 02/098302	12/2002
WO	WO 03/013363	2/2003
WO	WO 03/013364	2/2003
WO	WO 03/047434	6/2003
WO	WO 03/071955	9/2003
WO	WO 03/071956	9/2003
WO	WO 03/071957	9/2003
WO	WO 03/094748	11/2003
WO	WO 03/101310	12/2003
WO	WO 2004/004578	1/2004
WO	WO 2004/012602	2/2004
WO	WO 2004/060169	7/2004
WO	WO 2004/069054	8/2004
WO	WO 2005/000126	1/2005
WO	WO 2005/006990	1/2005
WO	WO 2005/041782	5/2005
WO	WO 2005/063129	7/2005
WO	WO 2005/082256	9/2005
WO	WO 2005/092204	10/2005
WO	WO 2005/110240	11/2005
WO	WO 2005/112782	12/2005
WO	WO 2005/115251	12/2005
WO	WO 2005/115521	12/2005
WO	WO 2006/000514	1/2006
WO	WO 2006/026116	3/2006
WO	WO 2006/052611	5/2006
WO	WO 2006/052612	5/2006
WO	WO 2006/078578	7/2006
WO	WO 2006/083889	8/2006
WO	WO 2006/115901	11/2006
WO	WO 2006/115904	11/2006
WO	WO 2006/118877	11/2006
WO	WO 2007/005585	1/2007
WO	WO 2007/025014	3/2007
WO	WO 2007/081836	7/2007
WO	WO 2007/088069	8/2007
WO	WO 2008/031102	3/2008
WO	WO 2008/036384	3/2008
WO	WO 2008/074027	6/2008
WO	WO 2008/150915	12/2008
WO	WO 2009/079091	6/2009
WO	WO 2010/062693	6/2010
WO	WO 2010/081101	7/2010
WO	WO 2010/081102	7/2010
WO	WO 2010/081103	7/2010
WO	WO 2010/081106	7/2010
ZA	200100527	1/2001
ZA	200100528	1/2001

OTHER PUBLICATIONS

U.S. Appl. No. 09/610,128, filed Jul. 5, 2000, Kerievsky.
U.S. Appl. No. 09/866,551, filed May 25, 2001, Ginn.
U.S. Appl. No. 12/113,092, filed Apr. 30, 2008, Ginn et al.
U.S. Appl. No. 13/017,636, filed Jan. 31, 2011, Carley et al.
U.S. Appl. No. 60/693,531, filed Jun. 24, 2005, Carly.
U.S. Appl. No. 60/696,069, filed Jul. 1, 2005, Pantages et al.
U.S. Appl. No. 60/793,444, filed Apr. 20, 2006, Jones et al.
U.S. Appl. No. 60/946,026, filed Jun. 25, 2007, Ellingwood.
U.S. Appl. No. 60/946,030, filed Jun. 25, 2007, Voss et al.
U.S. Appl. No. 60/946,042, filed Jun. 25, 2007, Ellingwood et al.
U.S. Appl. No. 61/015,144, filed Dec. 19, 2007, Mackiewicz et al.
U.S. Appl. No. 61/109,822, filed Oct. 30, 2008, Mehl et al.
U.S. Appl. No. 61/139,995, filed Dec. 22, 2008, Clark.
U.S. Appl. No. 61/141,597, filed Dec. 30, 2008, Clark.
U.S. Appl. No. 61/143,748, filed Jan. 9, 2009, Mehl et al.
U.S. Appl. No. 61/143,751, filed Jan. 9, 2009, Voss et al.
U.S. Appl. No. 61/145,468, filed Jan. 16, 2009, Fortson, et al.
U.S. Appl. No. 14/839,658, filed Aug. 31, 2015, Cummins et al.
U.S. Appl. No. 14/855,080, filed Sep. 15, 2015, Voss et al.
"Hand tool for forming telephone connections—comprises pliers with reciprocably driven ram crimping clip around conductors against anvil", Derwent-ACC-No. 1978-B8090A. (Jan. 10, 1978).
Carpenter et al, Midterm results of the multicenter trial of the Powerlink bifurcated system for endovascular aortic aneurysm repair, Journal of Vascular Surgery, vol. 40, No. 5, Nov. 2004, p. 849-859.e5.
Database WPI; Section PQ, Week 200120; Derwent Publications Ltd., London GB; Class P31, AN 2001-203165; XP002199926 & ZA 200 100 528 A (Anthony T), Feb. 28, 2001 abstract.
Deepak Mital et al, Renal Transplantation Without Sutures Using The Vascular Clipping System for Renal Artery and Vein Anastomosis—A New Technique, Transplantation Issue, Oct. 1996, pp. 1171-1173, vol. 62—No. 8, Section of Transplantation Surgery, Department of General Surgery, Rush-Presbyterian/St. Luke's Medical Center, Chigago, IL.
DL Wessel et al, Outpatient closure of the patent ductus arteriosus, Circulation, May 1988, pp. 1068-1071, vol. 77—No. 5, Department of Anesthesia, Children's Hospital, Boston, MA.
Eisenack et al, Percutaneous Endovascular Aortic Aneurysm Repair: A Prospective Evaluation of Safety, Efficiency, and Risk Factors, Journal of Endovascular Ther., 2009, vol. 16, p. 708-713.
E Pikoulis et al, Arterial reconstruction with vascular clips is safe and quicker than sutured repair, Cardiovascular Surgery, Dec. 1998, pp. 573-578(6), vol. 6—No. 6, Department of Surgery, Uniformed Services University of the Health Sciences, Bethesda, MD.
G Gershony et al, Novel vascular sealing device for closure of percutaneous vascular access sites, Cathet. Cardiovasc. Diagn., Jan. 1998, pp. 82-88, vol. 45.

(56) **References Cited**

OTHER PUBLICATIONS

Greenhalgh et al, Endovascular versus open repair of abdominal aortic aneurysm, The New England journal of medicine, vol. 362, No. 20, 2010, p. 1863-1871.
H De Swart et al, A new hemostatic puncture closure device for the immediate sealing of arterial puncture sites, American journal of cardiology, Aug. 1993, pp. 445-449, vol. 72—No. 5, Department of Cardiology Academic Hospital Maastricht, The Netherlands.
Harrith M. Hasson M.D. , Laparoscopic Cannula Cone with Means for Cannula Stabilization and Wound Closure, The Journal of the American Association of Gynecologic Laparoscopists, May 1998, pp. 183-185, vol. 5—No. 2, Division of Obstetrics and Gynecology, University of Chicago, Chigago, IL.
Howell et al, Percutaneous Repair of Abdominal Aortic Aneurysms Using the aneuRx Stent Graft and the Percutaneous Vascular Surgery Device, Catheterization and cardiovascular interventions, vol. 55, No. 3, 2002, p. 281-287.
Inlet Medical Inc. Brochure, pp. 1-2, referencing Om Elashry et al, Comparative clinical study of port-closure techniques following laparoscopic surgery, Department of Surgery, Mallickrodt Institute of Radiography, J Am Coll Surg., Oct. 1996, pp. 335-344, vol. 183—No. 4.
Jean-Baptiste et al., Percutaneous closure devices for endovascular repair of infrarenal abdominal aortic aneurysms: a prospective, non-randomized comparative study, European Journal of Vascular and Endovascular Surgery, vol. 35, No. 4, 2008, p. 422-428.
J. Findlay et al, Carotid Arteriotomy Closure Using a Vascular Clip System, Neurosurgery, Mar. 1998, pp. 550-554, vol. 42—No. 3, Division of Neurosurgery, University of Alberta, Edmonton, Canada.
Jeremy L Gilbert PHD, Wound Closure Biomaterials and Devices, Shock., Mar. 1999, p. 226, vol. 11—No. 3, Institution Northwestern University (editorial review).
Jochen T. Cremer, MD, et al, Different approaches for minimally invasive closure of atrial septal defects, Ann. Thorac. Surg., Nov 1998, pp. 1648-1652, vol. 67, a Division of Thoracic and Cardiovascular Surgery, Surgical Center, Hannover Medical School. Hannover, Germany.
K Narayanan et al, Simultaneous primary closure of four fasciotomy wounds in a single setting using the Sure-Closure device, Injury, Jul. 1996, pp. 449-451, vol. 27—No. 6, Department of Surgery, Mercy Hospital of Pittsburgh, PA.
Krajcer and Gregoric, Totally percutaneous aortic aneurysm repair: methods and outcomes using the fully integrated intuiTrak endovascular system, The Journal of cardiovascular surgery, vol. 51, No. 4, 2010, p. 493-501.
Lederle et al, Outcomes following endovascular vs open repair of abdominal aortic aneurysm: a randomized trial, Jama, vol. 302, No. 14, 2009, p. 1535-1542
Lee et al, Total percutaneous access for endovascular aortic aneurysm repair ("Predose" technique), Journal of vascular surgery, vol. 45, No. 6, 2007, p. 1095-1101.
Malkawi et al, Percutaneous access for endovascular aneurysm repair: a systematic review, European Journal of Vascular and Endovascular Surgery, vol. 39, No. 6, 2010, p. 676-682.
Marshall A.C., Lock J.E., Structural and Compliant Anatomy of the Patent Foramen Ovale in Patients Undergoing Transcatheter Closure, Am Heart J Aug. 2000; 140(2); pp. 303-307.
MD Gonze et al, Complications associated with percutaneous closure devices, Conference: Annual Meeting of the Society for Clinical Vascular Surgery, The American journal of surgery, Mar. 1999, pp. 209-211, vol. 178, No. 3, Department of Surgery, Section of Vascular Surgery, Ochsner Medical Institutions, New Orleans, LA.
MD Hellinger et al, Effective peritoneal and fascial closure of abdominal trocar sites utilizing the Endo-Judge, J Laparoendosc Surg., Oct. 1996, pp. 329-332, vol. 6—No. 5, Orlando Regional Medical Center, FL.
Michael Gianturco, A Play on Catheterization, Forbes, Dec. 1996, p. 146, vol. 158—No. 15.
Morasch et al, Percutaneous repair of abdominal aortic aneurysm, Journal of vascular surgery, Vol, 40, No. 1, 2004, p. 12-16.
P M N Werker, et al, Review of facilitated approaches to vascular anastomosis surgery, Conference: Utrecht MICABG Workshop 2, The Annals of thoracic surgery, Apr. 1996, pp. S122-127, vol. 63—No. 6, Department of Plastic, Reconstructive and Hand surgery, University Hospital Utrecht Netherlands Departments of Cardiology and Cardiopulmonary Surgery, Heart Lung Institute, Utrecht Netherlands.; Utrect University Hospital Utrecht Netherlands.
Peter Rhee MD et al, Use of Titanium Vascular Staples in Trauma, Journal of Trauma-Injury Infection & Critical Care, Dec. 1998, pp. 1097-1099, vol. 45—No. 6, Institution from the Department of Surgery, Washington Hospital Center, Washington DC, and Uniformed Services University of the Health Sciences, Bethesda, Maryland.
ProstarXL—Percutaneous Vascular Surgical Device, www.Archive.org, Jun. 1998, Original Publisher: http://prostar.com, may also be found at http://web.archive.org/web/19980630040429/www.perclose.com/html/prstrxl.html.
Rachel et al, Percutaneous endovascular abdominal aortic aneurysm repair, Annals of vascular surgery, vol. 16, No. 1, 2002, p. 43-49.
SA Beyer-Enke et al, Immediate sealing of arterial puncture site following femoropopliteal angioplasty: A prospective randomized trial, Cardiovascular and Interventional Radiology 1996, Nov.-Dec. 1996, pp. 406-410, vol. 19—No. 6, Gen Hosp North, Dept Dianost & Intervent Radiol, Nurnberg, Germany (Reprint).
Scott Hensley, Closing Wounds. New Devices seal arterial punctures in double time, Modern Healthcare (United States), Mar. 23, 2008, p. 48.
Sigmund Silber et al, A novel vascular device for closure of percutaneous arterial access sites, The American Journal of Cardiology, Apr. 1999, pp. 1248-1252, vol. 83—No. 8.
Simonetta Blengino et al, A Randomized Study of the 8 French Hemostatic Puncture Closure Device vs Manual Compression After Coronary Interventions, Journal of the American College of Cardiology, Feb. 1995, p. 262A, vol. 25.—No. 2, Supplement 1.
Starnes et al, Totally percutaneous aortic aneurysm repair: experience and prudence, Journal of vascular surgery, vol. 43, No. 2, 2006, p. 270-276.
Stretch Comb by Scunci, retrieved via internet at www.scunci.com/productdetail by examiner on Oct. 9, 2007, publication date unavailable.
Swee Lian Tan, MD, PHD, FACS, Explanation of Infected Hemostatic Puncture Closure Devices—A Case Report, Vascular and Endovascular Surgery, 1999, pp. 507-510, vol. 33—No. 5, Parkland Medical Center, Derry, New Hampshire.
Sy Nakada et al, Comparison of newer laparoscopic port closure techniques in the porcine model, J Endourol, Oct. 1995, pp. 397-401, vol. 9—No. 5, Department of Surgery/Urology, University of Wisconsin Medical School, Madison.
Taber's Cyclopedic Medical Dictionary, 18th Ed. 1997, pp. 747 and 1420.
Teh et al, Use of the percutaneous vascular surgery device for closure of femoral access sites during endovascular aneurysm repair: lessons from our experience, European Journal of Vascular and Endovascular Surgery, vol. 22, No. 5, 2001, pp. 418-423.
Thomas P. Baum RPA-C et al, Delayed Primary Closure Using Silastic Vessel Loops and Skin Staples: Description of the Technique and Case Reports, Annals of Plastic Surgery, Mar. 1999, pp. 337-340, vol. 42—No. 3, Institution Department of Plastic and Reconstructive Surgery, Albert Einstein College of Medicine and Montefiore Medical Center, Bronx, NY.
Tomoaki Hinohara, Percutaneous vascular surgery (Prostar® Plus and Techstar® for femoral artery site closure), Interventional Cardiology Newsletter, May-Jul. 1997, pp. 19-22, pp. 24-28, vol. 5—No. 3-4.
Torsello et al, Endovascular suture versus cutdown for endovascular aneurysm repair: a prospective randomized pilot study, Journal of vascular surgery, vol. 38, No. 1, 2003, p. 78-82.
Traul et al, Percutaneous endovascular repair of infrarenal abdominal aortic aneurysms: a feasibility study, Journal of vascular surgery, vol. 32, No. 4, 2000, p. 770-776.
Ut Aker et al, Immediate arterial hemostasis after cardiac catheterization: initial experience with a new puncture closure device, Cathet Cardiovasc Diagn, Mar. 1994, pp. 228-232, vol. 33—No. 3, Missouri Baptist Medical Center, St. Louis.

(56) **References Cited**

OTHER PUBLICATIONS

Watelet et al, Percutaneous repair of aortic aneurysms: a prospective study of suture-mediated closure devices, European journal of vascular and endovascular surgery, vol. 32, No. 3, 2006, p. 261-265.
Wei Qu et al, An absorbable pinned-ring device for microvascular anastomosis of vein grafts: Experimental studies, Microsurgery 1999, Mar. 1999, pp. 128-134, vol. 19—No. 3, Department of Orthopaedic Surgery, Hiroshima University School of Medicine, Hiroshima, Japan.
William G. Kussmaul Iii Md, et al., Rapid arterial hemostasis and decreased access site complications after cardiac catheterization and angioplasty: Results of a randomized trial of a novel hemostatic device, Journal of the American College of Cardiology, Jun. 1995, pp. 1685-1692, vol. 25—No. 7.
U.S. Appl. No. 09/478,179, Nov. 6, 2000, Notice of Allowance.
U.S. Appl. No. 09/546,998, May 6, 2002, Notice of Allowance.
U.S. Appl. No. 09/610,238, Mar. 26, 2001, Notice of Allowance.
U.S. Appl. No. 09/610,238, Sep. 5, 2001, Office Action.
U.S. Appl. No. 09/610,238, Feb. 11, 2002, Notice of Allowance.
U.S. Appl. No. 09/680,837, Jul. 9, 2002, Office Action.
U.S. Appl. No. 09/680,837, Nov. 6, 2002, Office Action.
U.S. Appl. No. 09/680,837, Mar. 25, 2003, Office Action.
U.S. Appl. No. 09/680,837, Jun. 16, 2003, Notice of Allowance.
U.S. Appl. No. 09/732,178, Aug. 1, 2002, Office Action.
U.S. Appl. No. 09/732,178, Dec. 24, 2002, Office Action.
U.S. Appl. No. 09/732,178, Jun. 10, 2003, Office Action.
U.S. Appl. No. 09/732,178, Jul. 3, 2003, Office Action.
U.S. Appl. No. 09/732,178, Nov. 17, 2003, Notice of Allowance.
U.S. Appl. No. 09/732,835, Sep. 11, 2003, Office Action.
U.S. Appl. No. 09/732,835, Feb. 9, 2004, Office Action.
U.S. Appl. No. 09/732,835, Mar. 17, 2004, Notice of Allowance.
U.S. Appl. No. 09/764,813, Mar. 26, 2001, Office Action.
U.S. Appl. No. 09/764,813, Jun. 4, 2001, Notice of Allowance.
U.S. Appl. No. 09/933,299, Feb. 26, 2003, Office Action.
U.S. Appl. No. 09/933,299, Jun. 16, 2003, Notice of Allowance.
U.S. Appl. No. 09/948,813, Jan. 31, 2003, Notice of Allowance.
U.S. Appl. No. 09/949,398, Mar. 4, 2003, Office Action.
U.S. Appl. No. 09/949,398, Jul. 28, 2003, Notice of Allowance.
U.S. Appl. No. 09/949,438, Dec. 17, 2002, Office Action.
U.S. Appl. No. 09/949,438, Apr. 21, 2003, Notice of Allowance.
U.S. Appl. No. 10/006,400, Aug. 27, 2004, Office Action.
U.S. Appl. No. 10/006,400, Feb. 23, 2005, Office Action.
U.S. Appl. No. 10/006,400, Apr. 11, 2005, Office Action.
U.S. Appl. No. 10/006,400, Jul. 27, 2005, Office Action.
U.S. Appl. No. 10/006,400, Mar. 6, 2006, Office Action.
U.S. Appl. No. 10/006,400, May 24, 2006, Office Action.
U.S. Appl. No. 10/006,400, Oct. 26, 2006, Office Action.
U.S. Appl. No. 10/006,400, Apr. 19, 2007, Office Action.
U.S. Appl. No. 10/006,400, Apr. 2, 2008, Office Action.
U.S. Appl. No. 10/006,400, Jan. 2, 2009, Office Action.
U.S. Appl. No. 10/006,400, Jul. 9, 2009, Notice of Allowance.
U.S. Appl. No. 10/006,400, Jan. 13, 2010, Notice of Allowance.
U.S. Appl. No. 10/006,400, Apr. 27, 2010, Notice of Allowance.
U.S. Appl. No. 10/006,400, Aug. 2, 2010, Notice of Allowance.
U.S. Appl. No. 10/081,717, Sep. 29, 2003, Notice of Allowance.
U.S. Appl. No. 10/081,723, Sep. 29, 2004, Office Action.
U.S. Appl. No. 10/081,723, May 13, 2005, Notice of Allowance.
U.S. Appl. No. 10/081,725, Feb. 9, 2004, Notice of Allowance.
U.S. Appl. No. 10/081,725, Apr. 13, 2004, Office Action.
U.S. Appl. No. 10/081,726, Apr. 11, 2003, Notice of Allowance.
U.S. Appl. No. 10/081,726, Jun. 9, 2003, Notice of Allowance.
U.S. Appl. No. 10/147,774, Nov. 4, 2004, Office Action.
U.S. Appl. No. 10/147,774, May 4, 2005, Office Action.
U.S. Appl. No. 10/147,774, Oct. 18, 2005, Office Action.
U.S. Appl. No. 10/147,774, Apr. 18, 2007, Notice of Allowance.
U.S. Appl. No. 10/147,774, Sep. 27, 2007, Notice of Allowance.
U.S. Appl. No. 10/147,774, Feb. 4, 2008, Notice of Allowance.
U.S. Appl. No. 10/147,774, Jun. 30, 2008, Office Action.
U.S. Appl. No. 10/147,774, Mar. 18, 2009, Office Action.
U.S. Appl. No. 10/147,774, Oct. 26, 2009, Office Action.
U.S. Appl. No. 10/147,774, Jun. 8, 2010, Office Action.
U.S. Appl. No. 10/147,774, Dec. 2, 2010, Notice of Allowance.
U.S. Appl. No. 10/240,183, Jul. 27, 2004, Office Action.
U.S. Appl. No. 10/240,183, Dec. 17, 2004, Office Action.
U.S. Appl. No. 10/240,183, Mar. 9, 2005, Notice of Allowance.
U.S. Appl. No. 10/240,183, Aug. 11, 2006, Office Action.
U.S. Appl. No. 10/264,306, Feb. 9, 2005, Office Action.
U.S. Appl. No. 10/264,306, Oct. 4, 2005, Office Action.
U.S. Appl. No. 10/264,306, May 10, 2006, Notice of Allowance.
U.S. Appl. No. 10/264,306, Jul. 2, 2007, Notice of Allowance.
U.S. Appl. No. 10/264,306, Feb. 4, 2008, Notice of Allowance.
U.S. Appl. No. 10/264,306, Jun. 27, 2008, Office Action.
U.S. Appl. No. 10/264,306, Feb. 26, 2009, Office Action.
U.S. Appl. No. 10/264,306, Aug. 13, 2009, Office Action.
U.S. Appl. No. 10/264,306, Jan. 27, 2010, Office Action.
U.S. Appl. No. 10/264,306, Jun. 15, 2010, Office Action.
U.S. Appl. No. 10/264,306, Oct. 29, 2010, Notice of Allowance.
U.S. Appl. No. 10/335,075, Aug. 10, 2005, Office Action.
U.S. Appl. No. 10/335,075, Dec. 19, 2005, Office Action.
U.S. Appl. No. 10/335,075, Apr. 21, 2006, Office Action.
U.S. Appl. No. 10/335,075, Dec. 27, 2006, Notice of Allowance.
U.S. Appl. No. 10/356,214, Nov. 30, 2005, Office Action.
U.S. Appl. No. 10/356,214, Aug. 23, 2006, Office Action.
U.S. Appl. No. 10/356,214, Feb. 13, 2007, Office Action.
U.S. Appl. No. 10/356,214, Sep. 12, 2007, Office Action.
U.S. Appl. No. 10/356,214, Mar. 6, 2008, Office Action.
U.S. Appl. No. 10/356,214, Nov. 4, 2008, Office Action.
U.S. Appl. No. 10/356,214, Apr. 29, 2009, Office Action.
U.S. Appl. No. 10/356,214, Jan. 13, 2010, Notice of Allowance.
U.S. Appl. No. 10/356,214, May 13, 2010, Notice of Allowance.
U.S. Appl. No. 10/356,214, Sep. 3, 2010, Notice of Allowance.
U.S. Appl. No. 10/435,104, Jun. 10, 2004, Office Action.
U.S. Appl. No. 10/435,104, Sep. 21, 2004, Notice of Allowance.
U.S. Appl. No. 10/435,104, Jan. 3, 2006, Examiner's Amendment.
U.S. Appl. No. 10/435,104, May 16, 2006, Office Action.
U.S. Appl. No. 10/435,104, Dec. 28, 2006, Notice of Allowance.
U.S. Appl. No. 10/435,104, Jul. 10, 2007, Notice of Allowance.
U.S. Appl. No. 10/435,104, Aug. 2, 2007, Notice of Allowance.
U.S. Appl. No. 10/435,104, Oct. 26, 2007, Notice of Allowance.
U.S. Appl. No. 10/435,104, Nov. 14, 2007, Notice of Allowance.
U.S. Appl. No. 10/435,104, Apr. 4, 2008, Notice of Allowance.
U.S. Appl. No. 10/435,104, Sep. 26, 2008, Notice of Allowance.
U.S. Appl. No. 10/435,104, Dec. 22, 2008, Notice of Allowance.
U.S. Appl. No. 10/435,104, Jul. 23, 2009, Notice of Allowance.
U.S. Appl. No. 10/435,104, Jan. 20, 2010, Notice of Allowance.
U.S. Appl. No. 10/435,104, Jun. 2, 2010, Office Action.
U.S. Appl. No. 10/435,104, Oct. 05, 2010, Notice of Allowance.
U.S. Appl. No. 10/455,768, Nov. 16, 2004, Office Action.
U.S. Appl. No. 10/455,768, Apr. 6, 2005, Notice of Allowance.
U.S. Appl. No. 10/486,067, Jan. 10, 2006, Office Action.
U.S. Appl. No. 10/486,067, Sep. 20, 2006, Notice of Allowance.
U.S. Appl. No. 10/486,070, Apr. 20, 2005, Office Action.
U.S. Appl. No. 10/486,070, Aug. 10, 2005, Office Action.
U.S. Appl. No. 10/486,070, Oct. 18, 2005, Notice of Allowance.
U.S. Appl. No. 10/517,004, Aug. 13, 2007, Office Action.
U.S. Appl. No. 10/517,004, Jan. 30, 2008, Office Action.
U.S. Appl. No. 10/517,004, Aug. 13, 2008, Notice of Allowance.
U.S. Appl. No. 10/517,004, Feb. 10, 2009, Notice of Allowance.
U.S. Appl. No. 10/517,004, Mar. 24, 2009, Notice of Allowance.
U.S. Appl. No. 10/517,004, Jun. 26, 2009, Notice of Allowance.
U.S. Appl. No. 10/517,004, Jan. 11, 2010, Notice of Allowance.
U.S. Appl. No. 10/517,004, Apr. 23, 2010, Notice of Allowance.
U.S. Appl. No. 10/517,004, Aug. 3, 2010, Notice of Allowance.
U.S. Appl. No. 10/519,778, Feb. 23, 2006, Office Action.
U.S. Appl. No. 10/519,778, May 31, 2006, Notice of Allowance.
U.S. Appl. No. 10/541,083, Oct. 16, 2007, Office Action.
U.S. Appl. No. 10/541,083, Oct. 31, 2007, Office Action.
U.S. Appl. No. 10/541,083, May 5, 2008, Office Action.
U.S. Appl. No. 10/541,083, Sep. 19, 2008, Notice of Allowance.
U.S. Appl. No. 10/541,083, Dec. 29, 2008, Notice of Allowance.
U.S. Appl. No. 10/541,083, Apr. 16, 2009, Notice of Allowance.
U.S. Appl. No. 10/541,083, Sep. 30, 2009, Notice of Allowance.
U.S. Appl. No. 10/541,083, Feb. 5, 2010, Notice of Allowance.

(56) **References Cited**

OTHER PUBLICATIONS

U.S. Appl. No. 10/541,083, May 10, 2010, Notice of Allowance.
U.S. Appl. No. 10/541,083, Aug. 17, 2010, Notice of Allowance.
U.S. Appl. No. 10/616,832, Jun. 30, 2006, Office Action.
U.S. Appl. No. 10/616,832, Oct. 20, 2006, Office Action.
U.S. Appl. No. 10/616,832, May 29, 2007, Office Action.
U.S. Appl. No. 10/616,832, Jan. 22, 2008, Office Action.
U.S. Appl. No. 10/616,832, Sep. 17, 2008, Office Action.
U.S. Appl. No. 10/616,832, Jul. 21, 2009, Office Action.
U.S. Appl. No. 10/616,832, Jan. 11, 2010, Notice of Allowance.
U.S. Appl. No. 10/616,832, May 12, 2010, Notice of Allowance.
U.S. Appl. No. 10/616,832, Sep. 20, 2010, Notice of Allowance.
U.S. Appl. No. 10/617,090, Mar. 22, 2005, Office Action.
U.S. Appl. No. 10/617,090, Jul. 6, 2005, Notice of Allowance.
U.S. Appl. No. 10/617,090, Oct. 5, 2005, Notice of Allowance.
U.S. Appl. No. 10/638,115, Sep. 22, 2006, Office Action.
U.S. Appl. No. 10/638,115, Jan. 31, 2007, Office Action.
U.S. Appl. No. 10/638,115, Sep. 18, 2007, Office Action.
U.S. Appl. No. 10/638,115, Feb. 7, 2008, Office Action.
U.S. Appl. No. 10/638,115, Oct. 29, 2008, Office Action.
U.S. Appl. No. 10/638,115, May 7, 2009, Notice of Allowance.
U.S. Appl. No. 10/638,115, Dec. 1, 2009, Notice of Allowance.
U.S. Appl. No. 10/638,115, Apr. 2, 2010, Notice of Allowance.
U.S. Appl. No. 10/638,115, Aug. 13, 2010, Notice of Allowance.
U.S. Appl. No. 10/667,144, Sep. 19, 2006 Office Action.
U.S. Appl. No. 10/667,144, May 2, 2007, Office Action.
U.S. Appl. No. 10/667,144, Nov. 19, 2007, Office Action.
U.S. Appl. No. 10/667,144, Dec. 5, 2007, Office Action.
U.S. Appl. No. 10/667,144, May 12, 2008, Office Action.
U.S. Appl. No. 10/667,144, Mar. 24, 2009, Office Action.
U.S. Appl. No. 10/667,144, Nov. 23, 2009, Office Action.
U.S. Appl. No. 10/667,144, Jun. 22, 2010, Office Action.
U.S. Appl. No. 10/667,144, Jun. 6, 2011, Office Action.
U.S. Appl. No. 10/667,144, Oct. 28, 2011, Notice of Allowance.
U.S. Appl. No. 10/669,313, Oct. 31, 2005, Office Action.
U.S. Appl. No. 10/669,313, Jan. 11, 2006, Notice of Allowance.
U.S. Appl. No. 10/669,313, Jun. 28, 2006, Notice of Allowance.
U.S. Appl. No. 10/682,459, Sep. 15, 2006, Office Action.
U.S. Appl. No. 10/682,459, Apr. 18, 2007, Office Action.
U.S. Appl. No. 10/682,459, Apr. 2, 2008, Office Action.
U.S. Appl. No. 10/682,459, Dec. 4, 2008, Office Action.
U.S. Appl. No. 10/682,459, Jun. 10, 2009, Office Action.
U.S. Appl. No. 10/682,459, Dec. 23, 2009, Office Action.
U.S. Appl. No. 10/682,459, Apr. 28, 2010, Office Action.
U.S. Appl. No. 10/682,459, Oct. 12, 2010, Office Action.
U.S. Appl. No. 10/682,459, Apr. 1, 2011, Notice of Allowance.
U.S. Appl. No. 10/786,444, Oct. 30, 2006, Office Action.
U.S. Appl. No. 10/786,444, Apr. 17, 2007, Office Action.
U.S. Appl. No. 10/786,444, Aug. 31, 2007, Office Action.
U.S. Appl. No. 10/786,444, Apr. 24, 2008, Office Action.
U.S. Appl. No. 10/786,444, Oct. 17, 2008, Office Action.
U.S. Appl. No. 10/786,444, Jun. 18, 2009, Office Action.
U.S. Appl. No. 10/786,444, Jan. 14, 2010, Office Action.
U.S. Appl. No. 10/786,444, Jul. 11, 2013, Notice of Allowance.
U.S. Appl. No. 10/787,073, Nov. 30, 2006, Office Action.
U.S. Appl. No. 10/787,073, Sep. 5, 2007, Office Action.
U.S. Appl. No. 10/787,073, Feb. 22, 2008, Office Action.
U.S. Appl. No. 10/787,073, Nov. 12, 2008, Office Action.
U.S. Appl. No. 10/787,073, Aug. 13, 2009, Office Action.
U.S. Appl. No. 10/787,073, Feb. 17, 2010, Notice of Allowance.
U.S. Appl. No. 10/787,073, Aug. 25, 2010, Notice of Allowance.
U.S. Appl. No. 10/908,721, Oct. 19, 2006, Office Action.
U.S. Appl. No. 10/908,721, Aug. 10, 2007, Office Action.
U.S. Appl. No. 10/908,721, Jan. 25, 2008, Office Action.
U.S. Appl. No. 10/908,721, Nov. 25, 2008, Office Action.
U.S. Appl. No. 10/908,721, Jun. 23, 2009, Office Action.
U.S. Appl. No. 10/908,721, Feb. 2, 2010, Office Action.
U.S. Appl. No. 10/908,721, Jul. 18, 2013, Notice of Allowance.
U.S. Appl. No. 11/048,503, Mar. 13, 2009, Office Action.
U.S. Appl. No. 11/048,503, Jun. 26, 2009, Office Action.
U.S. Appl. No. 11/048,503, Jan. 11, 2010, Notice of Allowance.
U.S. Appl. No. 11/048,503, Apr. 26, 2010, Notice of Allowance.
U.S. Appl. No. 11/048,503, Jul. 30, 2010, Notice of Allowance.
U.S. Appl. No. 11/113,549, Feb. 6, 2007, Office Action.
U.S. Appl. No. 11/113,549, May 30, 2007, Office Action.
U.S. Appl. No. 11/113,549, Nov. 9, 2007, Office Action.
U.S. Appl. No. 11/113,549, Apr. 16, 2008, Office Action.
U.S. Appl. No. 11/113,549, Jul. 21, 2009, Office Action.
U.S. Appl. No. 11/113,549, Jul. 6, 2010, Office Action.
U.S. Appl. No. 11/113,549, Jan. 4, 2011, Office Action.
U.S. Appl. No. 11/113,549, Mar. 14, 2014, Notice of Allowance.
U.S. Appl. No. 11/152,562, May 13, 2008, Office Action.
U.S. Appl. No. 11/152,562, Feb. 13, 2009, Office Action.
U.S. Appl. No. 11/152,562, Jul. 6, 2009, Office Action.
U.S. Appl. No. 11/152,562, Mar. 31, 2010, Office Action.
U.S. Appl. No. 11/152,562, Sep. 16, 2010, Notice of Allowance.
U.S. Appl. No. 11/198,811, Aug. 26, 2008, Office Action.
U.S. Appl. No. 11/198,811, Apr. 6, 2009, Office Action.
U.S. Appl. No. 11/198,811, Sep. 22, 2009, Office Action.
U.S. Appl. No. 11/198,811, Jun. 29, 2010, Notice of Allowance.
U.S. Appl. No. 11/344,793, Jan. 22, 2009, Office Action.
U.S. Appl. No. 11/344,868, Mar. 25, 2009, Office Action.
U.S. Appl. No. 11/344,891, Apr. 29, 2008, Office Action.
U.S. Appl. No. 11/344,891, Dec. 8, 2008, Office Action.
U.S. Appl. No. 11/344,891, Feb. 26, 2009, Office Action.
U.S. Appl. No. 11/344,891, Oct. 7, 2009, Office Action.
U.S. Appl. No. 11/344,891, May 7, 2010, Office Action.
U.S. Appl. No. 11/344,891, Jan. 22, 2013, Notice of Allowance.
U.S. Appl. No. 11/390,586, Jun. 24, 2009, Office Action.
U.S. Appl. No. 11/390,586, Jul. 6, 2010, Office Action.
U.S. Appl. No. 11/390,586, May 3, 2012, Notice of Allowance.
U.S. Appl. No. 11/396,141, May 22, 2009, Office Action.
U.S. Appl. No. 11/396,141, Aug. 26, 2009, Office Action.
U.S. Appl. No. 11/396141, May 4, 2010, Office Action.
U.S. Appl. No. 11/396,141, Apr. 30, 2013, Office Action.
U.S. Appl. No. 11/396,141, Aug. 21, 2013, Office Action.
U.S. Appl. No. 11/396,141, Nov. 4, 2013, Notice of Allowance.
U.S. Appl. No. 11/396,731, Feb. 13, 2009, Office Action.
U.S. Appl. No. 11/396,731, May 22, 2009, Office Action.
U.S. Appl. No. 11/396,731, Jun. 29, 2010, Office Action.
U.S. Appl. No. 11/396,731, Mar. 22, 2011, Office Action.
U.S. Appl. No. 11/396,731, Sep. 1, 2011, Office Action.
U.S. Appl. No. 11/396,731, Feb. 12, 2015, Office Action.
U.S. Appl. No. 11/396,731, Jul. 9, 2015, Notice of Allowance.
U.S. Appl. No. 11/406,203, May 14, 2007, Office Action.
U.S. Appl. No. 11/406,203, Jan. 29, 2008, Notice of Allowance.
U.S. Appl. No. 11/406,203, May 23, 2008, Notice of Allowance.
U.S. Appl. No. 11/406,203, Sep. 22, 2008, Notice of Allowance.
U.S. Appl. No. 11/406,203, Mar. 3, 2009, Office Action.
U.S. Appl. No. 11/406,203, Sep. 16, 2009, Office Action.
U.S. Appl. No. 11/406,203, Jun. 18, 2010, Notice of Allowance.
U.S. Appl. No. 11/411,925, Jun. 6, 2007, Office Action.
U.S. Appl. No. 11/411,925, Feb. 5, 2008, Office Action.
U.S. Appl. No. 11/411,925, Jan. 12, 2009, Office Action.
U.S. Appl. No. 11/411,925, Sep. 10, 2009, Office Action.
U.S. Appl. No. 11/411,925, Oct. 1, 2013, Office Action.
U.S. Appl. No. 11/411,925, Feb. 5, 2014, Notice of Allowance.
U.S. Appl. No. 11/427,297, Jan. 30, 2009, Office Action.
U.S. Appl. No. 11/427,297, Sep. 15, 2009, Office Action.
U.S. Appl. No. 11/427,297, Sep. 15, 2010, Office Action.
U.S. Appl. No. 11/427,297, Mar. 21, 2011, Office Action.
U.S. Appl. No. 11/427,297, Jun. 26, 2012, Notice of Allowance.
U.S. Appl. No. 11/427,309, May 28, 2008, Office Action.
U.S. Appl. No. 11/427,309, Jan. 2, 2009, Office Action.
U.S. Appl. No. 11/427,309, Apr. 20, 2009, Office Action.
U.S. Appl. No. 11/427,309, Nov. 6, 2009, Office Action.
U.S. Appl. No. 11/427,309, Apr. 26, 2010, Office Action.
U.S. Appl. No. 11/427,309, Nov. 15, 2010, Office Action.
U.S. Appl. No. 11/427,309, Jun. 7, 2013, Notice of Allowance.
U.S. Appl. No. 11/455,993, Feb. 17, 2009, Office Action.
U.S. Appl. No. 11/455,993, Dec. 16, 2009, Office Action.
U.S. Appl. No. 11/455,993, Jan. 29, 2014, Office Action.
U.S. Appl. No. 11/455,993, Aug. 11, 2014, Notice of Allowance.

(56) **References Cited**

OTHER PUBLICATIONS

U.S. Appl. No. 11/532,325, Feb. 23, 2009, Office Action.
U.S. Appl. No. 11/532,325, Jun. 17, 2009, Office Action.
U.S. Appl. No. 11/532,325, Jan. 5, 2010, Office Action.
U.S. Appl. No. 11/532,325, Jul. 17, 2013, Office Action.
U.S. Appl. No. 11/532,325, Dec. 2, 2013, Office Action.
U.S. Appl. No. 11/532,325, Jan. 16, 2015, Notice of Allowance.
U.S. Appl. No. 11/532,576, Mar. 1, 2010, Office Action.
U.S. Appl. No. 11/532,576, Apr. 23, 2010, Office Action.
U.S. Appl. No. 11/532,576, Oct. 13, 2010, Notice of Allowance.
U.S. Appl. No. 11/674930, Jan. 8, 2009, Office Action.
U.S. Appl. No. 11/674,930, Jun. 4, 2009, Office Action.
U.S. Appl. No. 11/674,930, Jan. 8, 2010, Office Action.
U.S. Appl. No. 11/674,930, Apr. 3, 2014, Notice of Allowance.
U.S. Appl. No. 11/675,462, Dec. 10, 2009, Office Action.
U.S. Appl. No. 11/675,462, Aug. 31, 2010, Office Action.
U.S. Appl. No. 11/675,462, Aug. 3, 2011, Office Action.
U.S. Appl. No. 11/675,462, Dec. 22, 2011, Notice of Allowance.
U.S. Appl. No. 11/744,089, Nov. 26, 2008, Office Action.
U.S. Appl. No. 11/744,089, Aug. 14, 2009, Office Action.
U.S. Appl. No. 11/744,089, Aug. 8, 2012, Office Action.
U.S. Appl. No. 11/744,089, Apr. 15, 2013, Office Action.
U.S. Appl. No. 11/744,089, Aug. 8, 2013, Notice of Allowance.
U.S. Appl. No. 11/757,108, Nov. 25, 2009, Office Action.
U.S. Appl. No. 11/767,818, Dec. 24, 2009, Office Action.
U.S. Appl. No. 11/767,818, Mar. 22, 2010, Office Action.
U.S. Appl. No. 11/767,818, Sep. 30, 2010, Office Action.
U.S. Appl. No. 11/767,818, Feb. 16, 2011, Office Action.
U.S. Appl. No. 11/767,818, Feb. 3, 2012, Notice of Allowance.
U.S. Appl. No. 11/852,190, Jun. 24, 2010, Office Action.
U.S. Appl. No. 11/852,190, Nov. 1, 2010, Office Action.
U.S. Appl. No. 11/852,190, Mar. 2, 2011, Office Action.
U.S. Appl. No. 11/852,190, Apr. 24, 2013, Office Action.
U.S. Appl. No. 11/852,190, Nov. 26, 2013, Office Action.
U.S. Appl. No. 11/852,190, Feb. 12, 2014, Notice of Allowance.
U.S. Appl. No. 11/958,281, Sep. 2, 2010, Office Action.
U.S. Appl. No. 11/958,281, Oct. 8, 2010, Office Action.
U.S. Appl. No. 11/958,281, Mar. 10, 2011, Office Action.
U.S. Appl. No. 11/958,295, Aug. 27, 2009, Office Action.
U.S. Appl. No. 11/958,295, May 25, 2010, Office Action.
U.S. Appl. No. 11/958,295, Jun. 13, 2014, Notice of Allowance.
U.S. Appl. No. 11/959,334, Aug. 19, 2009, Office Action.
U.S. Appl. No. 11/959,334, Jan. 12, 2010, Notice of Allowance.
U.S. Appl. No. 11/959,334, Apr. 14, 2010, Notice of Allowance.
U.S. Appl. No. 11/959,334, Jul. 23, 2010, Notice of Allowance.
U.S. Appl. No. 12/106,928, Jan. 23, 2009, Office Action.
U.S. Appl. No. 12/106,928, Oct. 5, 2009, Office Action.
U.S. Appl. No. 12/106,928, May 10, 2010, Office Action.
U.S. Appl. No. 12/106,928, Oct. 25, 2010, Office Action.
U.S. Appl. No. 12/106,928, Jun. 28, 2013, Office Action.
U.S. Appl. No. 12/106,928, Dec. 2, 2013, Office Action.
U.S. Appl. No. 12/106,928, Mar. 25, 2014, Advisory Action.
U.S. Appl. No. 12/106,928, Oct. 3, 2014, Notice of Allowance.
U.S. Appl. No. 12/106,937, Mar. 30, 2009, Office Action.
U.S. Appl. No. 12/106,937, Nov. 18, 2009, Office Action.
U.S. Appl. No. 12/106,937, Jun. 28, 2013, Office Action.
U.S. Appl. No. 12/106,937, Jan. 22, 2014, Office Action.
U.S. Appl. No. 12/106,937, Mar. 5, 2015, Notice of Allowance.
U.S. Appl. No. 12/113,851, Apr. 27, 2010, Office Action.
U.S. Appl. No. 12/113,851, Jun. 24, 2010, Office Action.
U.S. Appl. No. 12/113,851, Dec. 16, 2010, Office Action.
U.S. Appl. No. 12/113,851, Apr. 27, 2011, Office Action.
U.S. Appl. No. 12/113,851, Mar. 29, 2012, Office Action.
U.S. Appl. No. 12/113,851, Mar. 17, 2014, Office Action.
U.S. Appl. No. 12/113,851, Aug. 21, 2014, Office Action.
U.S. Appl. No. 12/113,851, Feb. 20, 2015, Notice of Allowance.
U.S. Appl. No. 12/114,031, Oct. 5, 2010, Office Action.
U.S. Appl. No. 12/114,031, Nov. 22, 2010, Office Action.
U.S. Appl. No. 12/114,031, May 11, 2011, Office Action.
U.S. Appl. No. 12/114,031, Aug. 2, 2011, Office Action.
U.S. Appl. No. 12/114,031, Mar. 6, 2012, Office Action.
U.S. Appl. No. 12/114,031, Mar. 10, 2014, Office Action.
U.S. Appl. No. 12/114,091, Oct. 27, 2010, Office Action.
U.S. Appl. No. 12/114,091, Dec. 17, 2010, Office Action.
U.S. Appl. No. 12/114,091, Jul. 7, 2011, Office Action.
U.S. Appl. No. 12/114,091, Apr. 5, 2012, Office Action.
U.S. Appl. No. 12/114,091, Nov. 8, 2012, Office Action.
U.S. Appl. No. 12/114,091, Feb. 12, 2015, Office Action.
U.S. Appl. No. 12/114,091, Jul. 23, 2015, Office Action.
U.S. Appl. No. 12/122,603, Mar. 3, 2011, Office Action.
U.S. Appl. No. 12/122,603, Apr. 22, 2011, Office Action.
U.S. Appl. No. 12/122,603, Sep. 23, 2011, Office Action.
U.S. Appl. No. 12/122,603, Nov. 20, 2013, Office Action.
U.S. Appl. No. 12/122,603, Apr. 30, 2014, Office Action.
U.S. Appl. No. 12/122,603, Apr. 9, 2015, Office Action.
U.S. Appl. No. 12/122,603, Sep. 23, 2015, Notice of Allowance.
U.S. Appl. No. 12/135,858, Jul. 13, 2011, Office Action.
U.S. Appl. No. 12/135,858, Feb. 16, 2012, Office Action.
U.S. Appl. No. 12/143,020, May 11, 2011, Office Action.
U.S. Appl. No. 12/143,020, Aug. 31, 2011, Office Action.
U.S. Appl. No. 12/143,020, Feb. 23, 2012, Notice of Allowance.
U.S. Appl. No. 12/338,977, Jan. 19, 2012, Office Action.
U.S. Appl. No. 12/338,977, Jul. 11, 2012, Office Action.
U.S. Appl. No. 12/338,977, Nov. 28, 2012, Office Action.
U.S. Appl. No. 12/338,977, Jun. 19, 2013, Office Action.
U.S. Appl. No. 12/393,877, Sep. 29, 2011, Office Action.
U.S. Appl. No. 12/393,877, Dec. 13, 2011, Office Action.
U.S. Appl. No. 12/393,877, May 21, 2012, Office Action.
U.S. Appl. No. 12/393,877, Aug. 4, 2014, Notice of Allowance.
U.S. Appl. No. 12/402,398, Mar. 9, 2010, Office Action.
U.S. Appl. No. 12/402,398, May 20, 2010, Office Action.
U.S. Appl. No. 12/402,398, Jan. 24, 2011, Office Action.
U.S. Appl. No. 12/402,398, Sep. 20, 2012, Office Action.
U.S. Appl. No. 12/402,398, Mar. 13, 2013, Notice of Allowance.
U.S. Appl. No. 12/403,256, Dec. 16, 2009, Office Action.
U.S. Appl. No. 12/403,256, Mar. 30, 2010, Office Action.
U.S. Appl. No. 12/403,256, Aug. 19, 2010, Notice of Allowance.
U.S. Appl. No. 12/403,277, Jul. 8, 2010, Office Action.
U.S. Appl. No. 12/403,277, Oct. 12, 2010, Office Action.
U.S. Appl. No. 12/403,277, Mar. 31, 2011, Office Action.
U.S. Appl. No. 12/403,277, Apr. 3, 2012, Office Action.
U.S. Appl. No. 12/403,277, Nov. 5, 2012, Office Action.
U.S. Appl. No. 12/403,277, Jan. 27, 2014, Office Action.
U.S. Appl. No. 12/403,277, Aug. 15, 2014, Office Action.
U.S. Appl. No. 12/481,377, Apr. 28, 2011, Office Action.
U.S. Appl. No. 12/481,377, Jun. 21, 2011, Office Action.
U.S. Appl. No. 12/481,377, Jan. 3, 2012, Office Action.
U.S. Appl. No. 12/481,377, Aug. 10, 2012, Notice of Allowance.
U.S. Appl. No. 12/548,274, Dec. 28, 2011, Office Action.
U.S. Appl. No. 12/548,274, Mar. 2, 2012, Office Action.
U.S. Appl. No. 12/548,274, Sep. 10, 2012, Office Action.
U.S. Appl. No. 12/548,274, Aug. 14, 2014, Office Action.
U.S. Appl. No. 12/608,769, Feb. 10, 2012, Office Action.
U.S. Appl. No. 12/608,769, Aug. 22, 2012, Office Action.
U.S. Appl. No. 12/608,769, Nov. 5, 2012, Notice of Allowance.
U.S. Appl. No. 12/608,773, Jun. 7, 2012, Office Action.
U.S. Appl. No. 12/608,773, Jul. 20, 2012, Office Action.
U.S. Appl. No. 12/608,773, Jan. 7, 2013, Office Action.
U.S. Appl. No. 12/608,773, Jul. 17, 2014, Office Action.
U.S. Appl. No. 12/608,773, Mar. 12, 2015, Office Action.
U.S. Appl. No. 12/608,773, Sep. 17, 2015, Notice of Allowance.
U.S. Appl. No. 12/642,319, Feb. 27, 2012, Office Action.
U.S. Appl. No. 12/642,319, Aug. 28, 2012, Office Action.
U.S. Appl. No. 12/642,319, Dec. 16, 2013, Office Action.
U.S. Appl. No. 12/642,319, May 27, 2014, Notice of Allowance.
U.S. Appl. No. 12/684,400, Feb. 13, 2012, Office Action.
U.S. Appl. No. 12/684,400, May 9, 2012, Office Action.
U.S. Appl. No. 12/684,400, Oct. 16, 2012, Office Action.
U.S. Appl. No. 12/684,400, Feb. 23, 2015, Office Action.
U.S. Appl. No. 12/684,400, Jul. 28, 2015, Notice of Allowance.
U.S. Appl. No. 12/684,470, Dec. 20, 2011, Office Action.
U.S. Appl. No. 12/684,470, Mar. 23, 2012, Office Action.
U.S. Appl. No. 12/684,470, Aug. 30, 2012, Office Action.

(56) **References Cited**

OTHER PUBLICATIONS

U.S. Appl. No. 12/684,470, Jun. 4, 2014, Office Action.
U.S. Appl. No. 12/684,470, Nov. 14, 2014, Office Action.
U.S. Appl. No. 12/684,470, Aug. 26, 2015, Office Action.
U.S. Appl. No. 12/684,542, Jan. 30, 2012, Office Action.
U.S. Appl. No. 12/684,542, Apr. 16, 2012, Office Action.
U.S. Appl. No. 12/684,542, Sep. 13, 2012, Office Action.
U.S. Appl. No. 12/684,542, Jun. 18, 2014, Office Action.
U.S. Appl. No. 12/684,542, Dec. 1, 2014, Office Action.
U.S. Appl. No. 12/684,562, Dec. 28, 2011, Office Action.
U.S. Appl. No. 12/684,562, Feb. 16, 2012, Office Action.
U.S. Appl. No. 12/684,562, Aug. 21, 2012, Office Action.
U.S. Appl. No. 12/684,562, Sep. 10, 2014, Office Action.
U.S. Appl. No. 12/684,562, Feb. 17, 2015, Notice of Allowance.
U.S. Appl. No. 12/684,569, Dec. 20, 2011, Office Action.
U.S. Appl. No. 12/684,569, Jan. 27, 2012, Office Action.
U.S. Appl. No. 12/684,569, Jul. 30, 2012, Office Action.
U.S. Appl. No. 12/684,569, Apr. 23, 2014, Office Action.
U.S. Appl. No. 12/688,065, Mar. 13, 2012, Office Action.
U.S. Appl. No. 12/688,065, Apr. 26, 2012, Office Action.
U.S. Appl. No. 12/688,065, Oct. 12, 2012, Office Action.
U.S. Appl. No. 12/688,065, Oct. 18, 2013, Office Action.
U.S. Appl. No. 12/688,065, Apr. 8, 2014, Office Action.
U.S. Appl. No. 12/724,304, Feb. 10, 2012, Office Action.
U.S. Appl. No. 12/848,642, Sep. 20, 2012, Office Action.
U.S. Appl. No. 12/848,642, Nov. 9, 2012, Office Action.
U.S. Appl. No. 12/848,642, Apr. 26, 2013, Office Action.
U.S. Appl. No. 12/848,642, Feb. 3, 2014, Notice of Allowance.
U.S. Appl. No. 12/850,242, Aug. 6, 2012, Office Action.
U.S. Appl. No. 12/850,242, Oct. 17, 2012, Office Action.
U.S. Appl. No. 12/850,242, Apr. 18, 2013, Office Action.
U.S. Appl. No. 12/850,242, Aug. 6, 2013, Notice of Allowance.
U.S. Appl. No. 12/897,358, Aug. 22, 2011, Office Action.
U.S. Appl. No. 12/897,358, Jan. 12, 2012, Notice of Allowance.
U.S. Appl. No. 12/897,358, Mar. 5, 2012, Notice of Allowance.
U.S. Appl. No. 12/941,809, Dec. 13, 2011, Office Action.
U.S. Appl. No. 12/941,809, Jan. 30, 2012, Office Action.
U.S. Appl. No. 12/941,809, Jun. 1, 2012, Office Action.
U.S. Appl. No. 12/941,809, Jul. 3, 2013, Office Action.
U.S. Appl. No. 12/941,809, Nov. 8, 2013, Office Action.
U.S. Appl. No. 12/941,809, Feb. 3, 2014, Notice of Allowance.
U.S. Appl. No. 12/945,646, Jan. 20, 2011, Office Action.
U.S. Appl. No. 12/945,646, Jul. 6, 2011, Office Action.
U.S. Appl. No. 12/945,646, Oct. 26, 2011, Office Action.
U.S. Appl. No. 12/945,646, Feb. 21, 2012, Notice of Allowance.
U.S. Appl. No. 12/950,628, Apr. 25, 2014, Notice of Allowance.
U.S. Appl. No. 12/955,859, May 26, 2011, Office Action.
U.S. Appl. No. 12/955,859, Jul. 21, 2011, Office Action.
U.S. Appl. No. 12/955,859, Dec. 15, 2011, Office Action.
U.S. Appl. No. 12/955,859, Aug. 6, 2012, Office Action.
U.S. Appl. No. 12/955,859, May 16, 2013, Office Action.
U.S. Appl. No. 12/955,859, Aug. 1, 2013, Notice of Allowance.
U.S. Appl. No. 12/961,331, Dec. 4, 2012, Office Action.
U.S. Appl. No. 12/961,331, Feb. 1, 2013, Office Action.
U.S. Appl. No. 12/961,331, Jul. 3, 2013, Office Action.
U.S. Appl. No. 12/961,331, Sep. 20, 2013, Advisory Action.
U.S. Appl. No. 12/961,331, Apr. 25, 2014, Notice of Allowance.
U.S. Appl. No. 12/966,923, Feb. 3, 2012, Notice of Allowance.
U.S. Appl. No. 12/973,204, Mar. 7, 2012, Notice of Allowance.
U.S. Appl. No. 12/987,792, Mar. 13, 2012, Office Action.
U.S. Appl. No. 12/987,792, Sep. 17, 2012, Office Action.
U.S. Appl. No. 12/987,792, Jan. 21, 2014, Office Action.
U.S. Appl. No. 12/987,792, Jun. 11, 2014, Office Action.
U.S. Appl. No. 12/987,792, Aug. 25, 2014, Notice of Allowance.
U.S. Appl. No. 13/026,989, Sep. 16, 2011, Office Action.
U.S. Appl. No. 13/026,989, Jun. 8, 2012, Office Action.
U.S. Appl. No. 13/026,989, Aug. 23, 2013, Office Action.
U.S. Appl. No. 13/030,922, Dec. 18, 2012, Office Action.
U.S. Appl. No. 13/030,922, Jan. 31, 2013, Office Action.
U.S. Appl. No. 13/030,922, Jul. 18, 2013, Office Action.
U.S. Appl. No. 13/030,922, Jan. 8, 2014, Notice of Allowance.
U.S. Appl. No. 13/039,087, Jul. 17, 2012, Office Action.
U.S. Appl. No. 13/039,087, Nov. 6, 2012, Notice of Allowance.
U.S. Appl. No. 13/112,618, Mar. 29, 2013, Office Action.
U.S. Appl. No. 13/112,618, Jun. 7, 2013, Office Action.
U.S. Appl. No. 13/112,618, Nov. 20, 2013, Office Action.
U.S. Appl. No. 13/112,618, Dec. 15, 2014, Office Action.
U.S. Appl. No. 13/112,618, May 18, 2015, Office Action.
U.S. Appl. No. 13/112,631, Mar. 29, 2013, Office Action.
U.S. Appl. No. 13/112,631, Jun. 26, 2013, Office Action.
U.S. Appl. No. 13/112,631, Dec. 2, 2013, Office Action.
U.S. Appl. No. 13/112,631, Nov. 20, 2014, Office Action.
U.S. Appl. No. 13/112,631, Apr. 15, 2015, Office Action.
U.S. Appl. No. 13/153,594, Jan. 29, 2013, Office Action.
U.S. Appl. No. 13/153,594, May 29, 2013, Office Action.
U.S. Appl. No. 13/153,594, Oct. 16, 2013, Notice of Allowance.
U.S. Appl. No. 13/222,899, Jan. 10, 2014, Office Action.
U.S. Appl. No. 13/222,899, Jul. 31, 2014, Office Action.
U.S. Appl. No. 13/222,899, Apr. 1, 2015, Office Action.
U.S. Appl. No. 13/222,899, Aug. 5, 2015, Office Action.
U.S. Appl. No. 13/308,227, Apr. 10, 2013, Office Action.
U.S. Appl. No. 13/308,227, Sep. 11, 2013, Office Action.
U.S. Appl. No. 13/308,227, Jul. 14, 2015, Office Action.
U.S. Appl. No. 13/488,233, Feb. 5, 2013, Notice of Allowance.
U.S. Appl. No. 13/490,143, Jan. 4, 2013, Office Action.
U.S. Appl. No. 13/490,143, Apr. 29, 2013, Notice of Allowance.
U.S. Appl. No. 13/525,839, Apr. 1, 2013, Office Action.
U.S. Appl. No. 13/525,839, Jul. 15, 2013, Notice of Allowance.
U.S. Appl. No. 13/615,547, Jan. 18, 2013, Office Action.
U.S. Appl. No. 13/615,547, Apr. 12, 2013, Notice of Allowance.
U.S. Appl. No. 13/791,829, May 29, 2013, Office Action.
U.S. Appl. No. 13/791,829, Oct. 8, 2013, Notice of Allowance.
U.S. Appl. No. 13/791,846, Jun. 4, 2015, Office Action.
U.S. Appl. No. 13/791,846, Oct. 27, 2015, Notice of Allowance.
U.S. Appl. No. 13/837,801, Dec. 16, 2015, Office Action.
U.S. Appl. No. 13/898,202, Jan. 3, 2014, Office Action.
U.S. Appl. No. 13/898,202, Aug. 21, 2014, Office Action.
U.S. Appl. No. 13/898,202, Feb. 10, 2015, Notice of Allowance.
U.S. Appl. No. 13/908,796, Jul. 21, 2015, Office Action.
U.S. Appl. No. 13/908,796, Nov. 6, 2015, Notice of Allowance.
U.S. Appl. No. 14/017,039, Jan. 23, 2015, Office Action.
U.S. Appl. No. 14/017,039, Jun. 10, 2015, Office Action.
U.S. Appl. No. 14/017,039, Oct. 27, 2015, Office Action.
U.S. Appl. No. 14/023,428, Jul. 27, 2015, Office Action.
U.S. Appl. No. 14/077,007, Jul. 27, 2015, Office Action.
U.S. Appl. No. 14/246,926, Aug. 5, 2015, Office Action.
U.S. Appl. No. 14/246,926, Nov. 23, 2015, Office Action.
U.S. Appl. No. 14/246,973, Aug. 3, 2015, Office Action.
U.S. Appl. No. 14/246,973, Nov. 24, 2015, Office Action.
U.S. Appl. No. 14/323,753, Nov. 3, 2015, Office Action.
U.S. Appl. No. 14/466,576, Jul. 8, 2015, Office Action.
U.S. Appl. No. 14/466,576, Dec. 15, 2015, Notice of Allowance.
U.S. Appl. No. 29/296,370, Aug. 18, 2008, Office Action.
U.S. Appl. No. 29/296,370, Dec. 2, 2008, Notice of Allowance.
U.S. Appl. No. 29/296,370, Apr. 1, 2009, Notice of Allowance.
U.S. Appl. No. 14/928,950, filed Oct. 30, 2015, Voss.
U.S. Appl. No. 15/056,821, filed Feb. 29, 2016, Palermo et al.
U.S. Appl. No. 15/069,230, filed Mar. 14, 2016, Kokish.
U.S. Appl. No. 12/684,470, filed Jan. 21, 2016, Office Action.
U.S. Appl. No. 13/112,618, filed Jan. 29, 2016, Office Action.
U.S. Appl. No. 13/222,899, filed Jan. 7, 2016, Notice of Allowance.
U.S. Appl. No. 13/308,227, filed Feb. 1, 2016, Notice of Allowance.
U.S. Appl. No. 13/908,796, filed Mar. 9, 2016, Issue Notification.
U.S. Appl. No. 14/023,428, Feb. 9, 2016, Office Action.
U.S. Appl. No. 14/077,007, Jan. 29, 2016, Office Action.
U.S. Appl. No. 14/312,339, Jan. 22, 2016, Office Action.
U.S. Appl. No. 14/539,830, Jan. 29, 2016, Office Action.

* cited by examiner

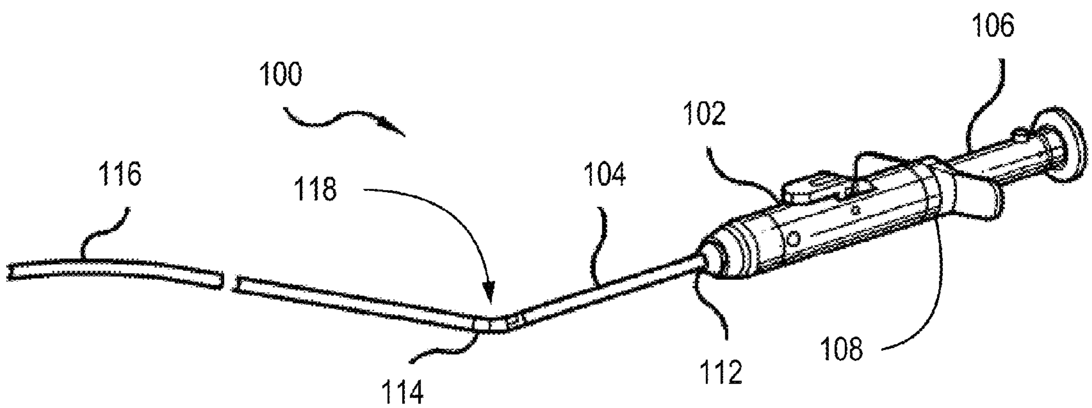


Fig. 1A

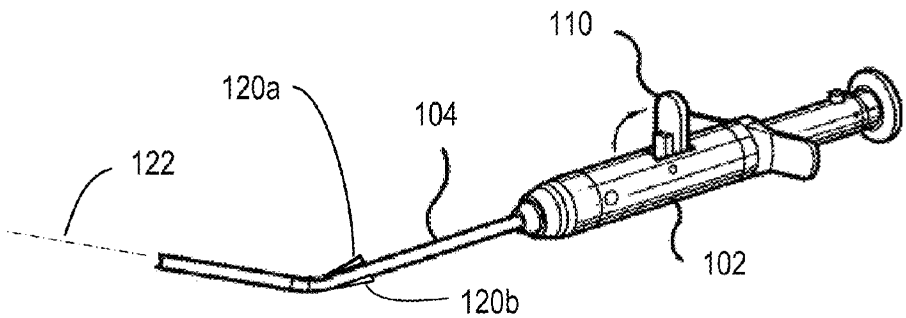
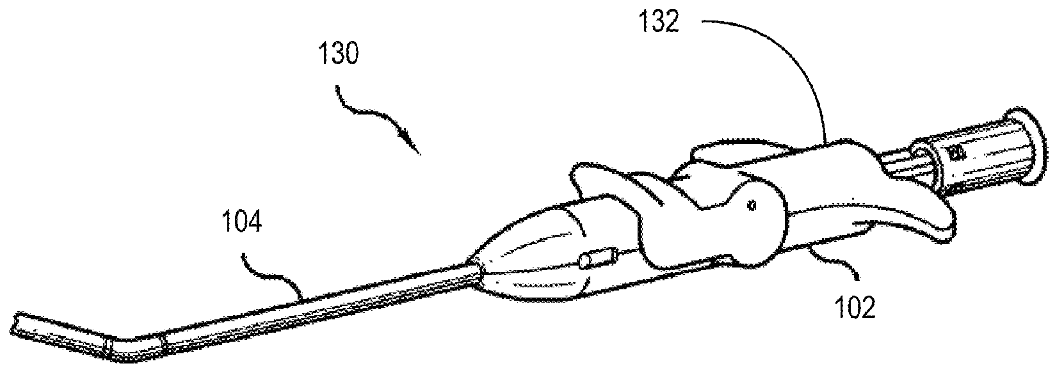


Fig. 1B



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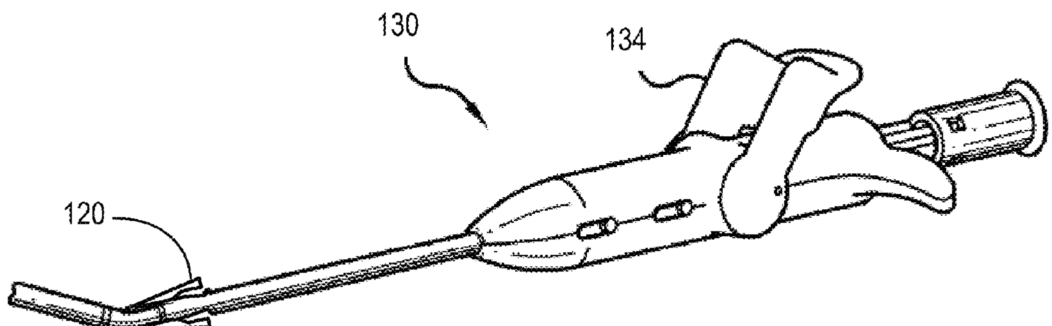

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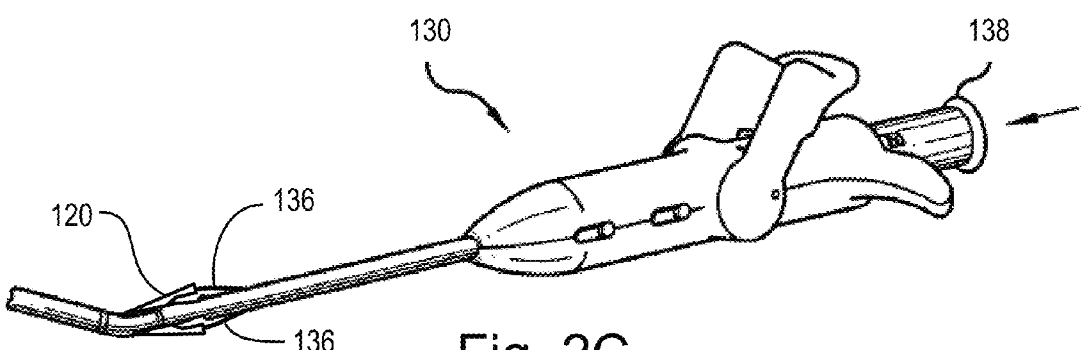

Fig. 2C

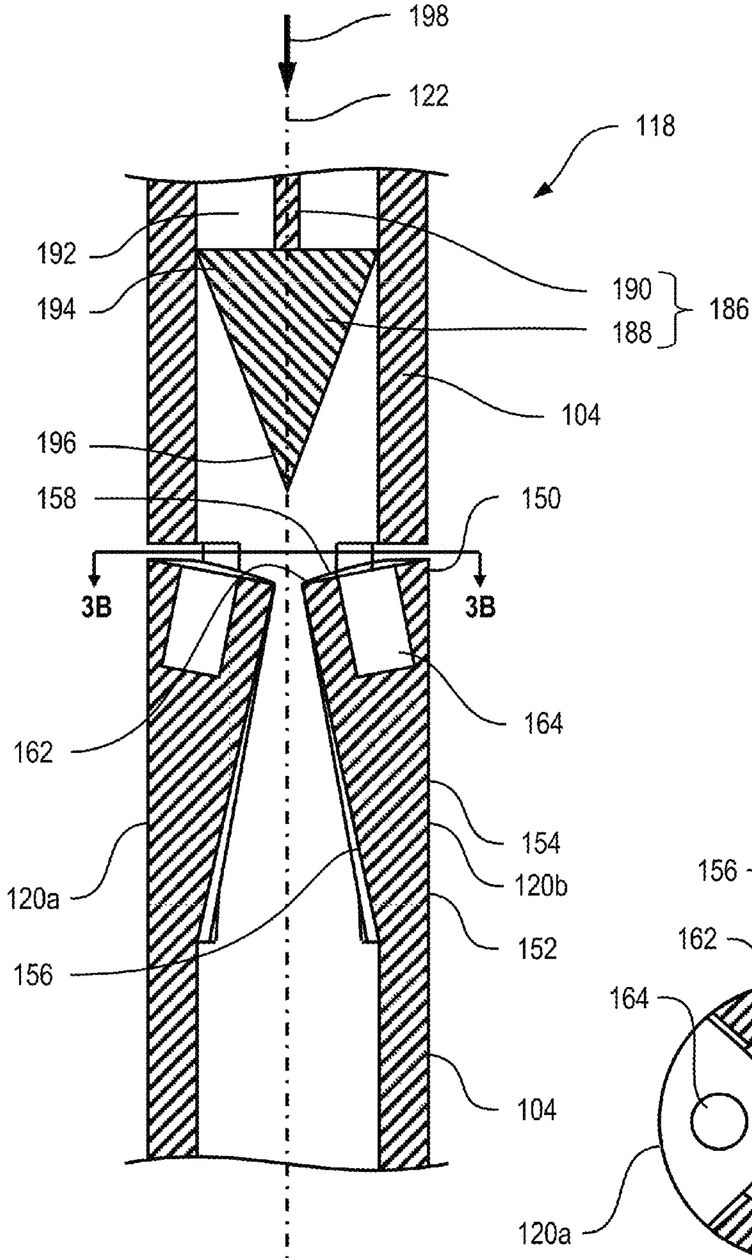
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Fig. 3A

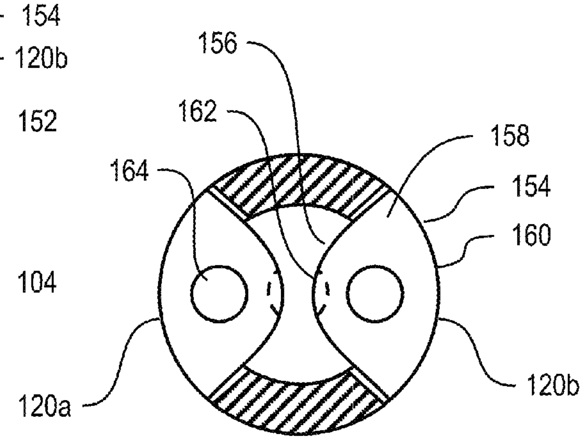
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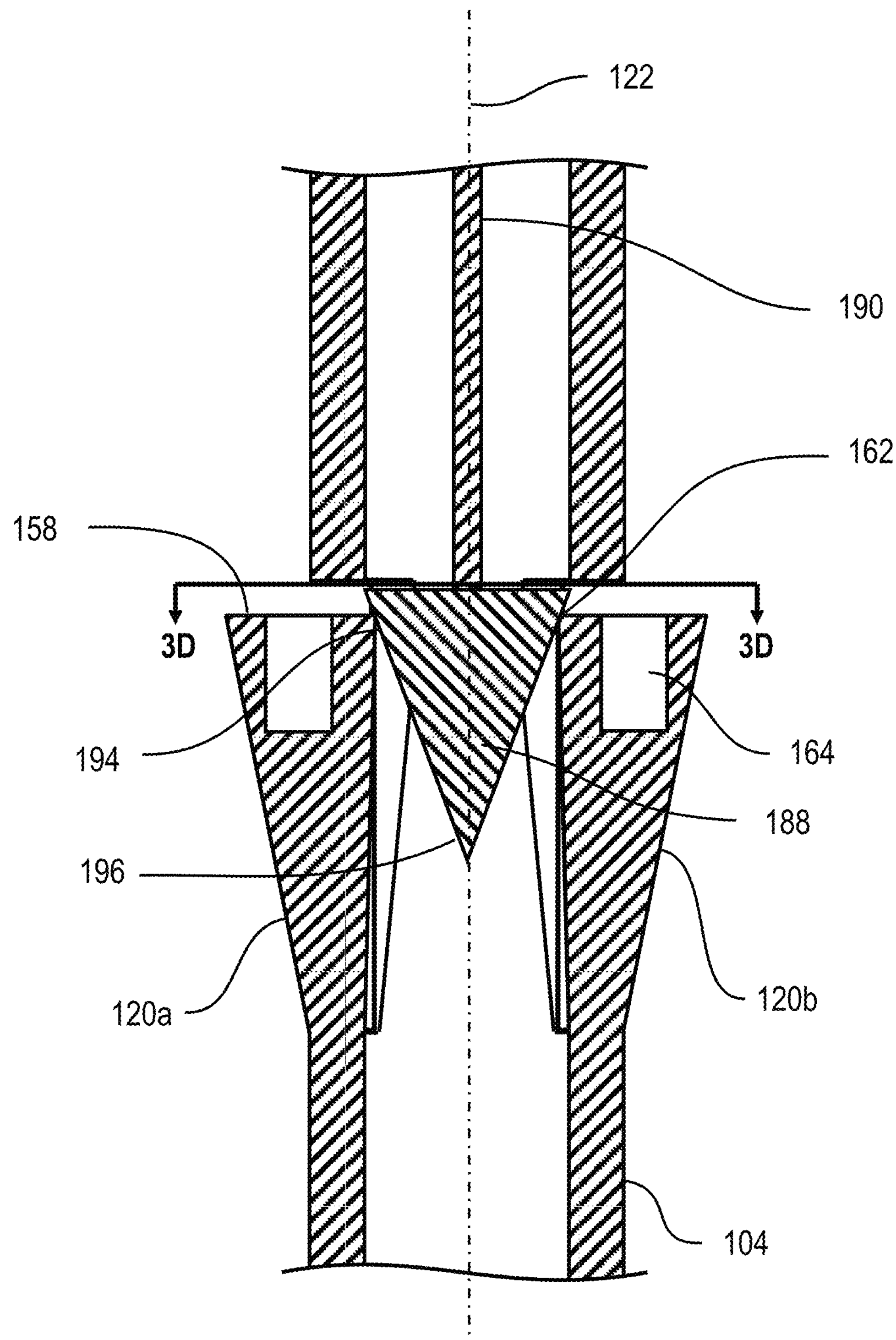
Fig. 3B



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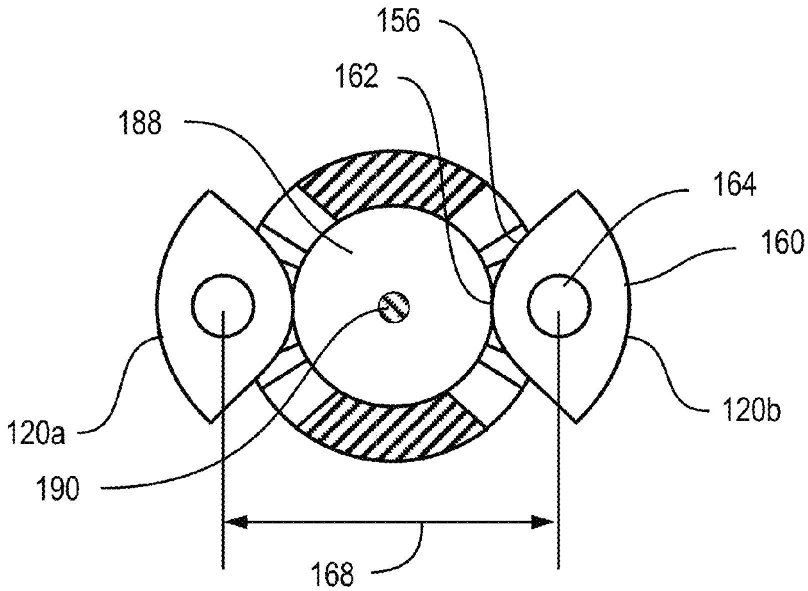


Fig. 3D

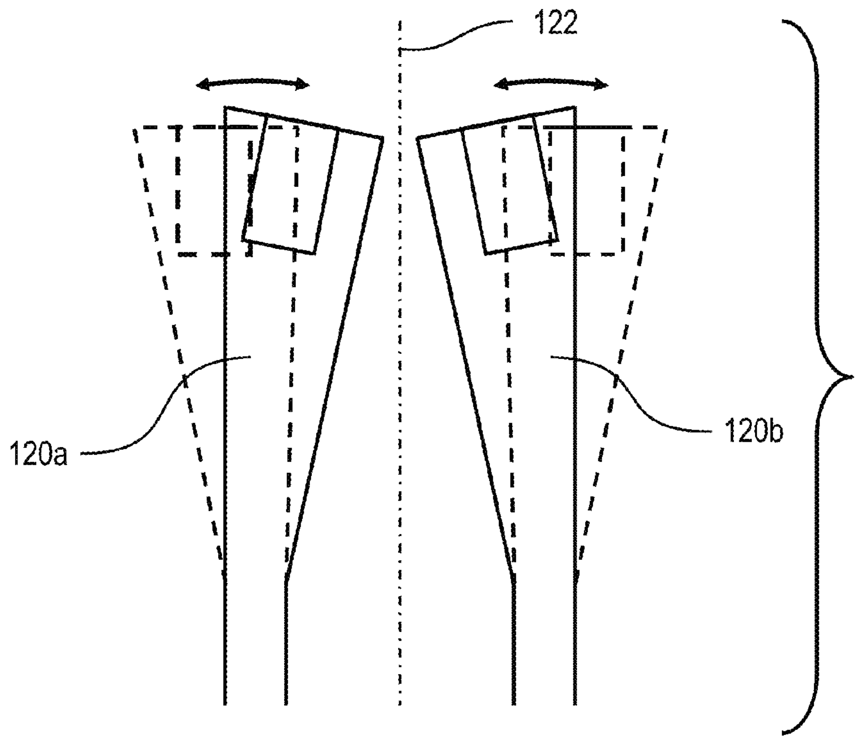


Fig. 3E

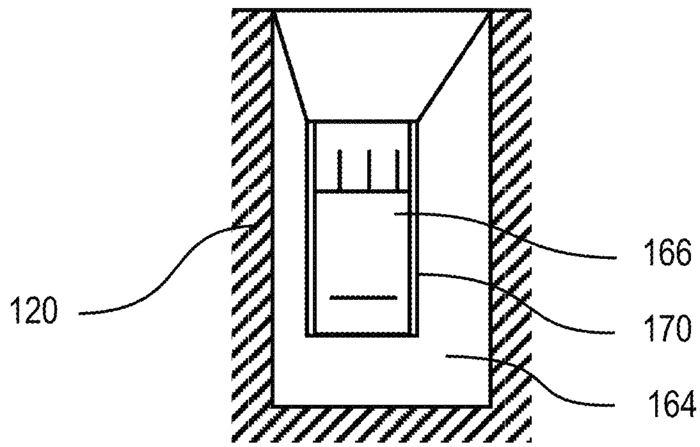
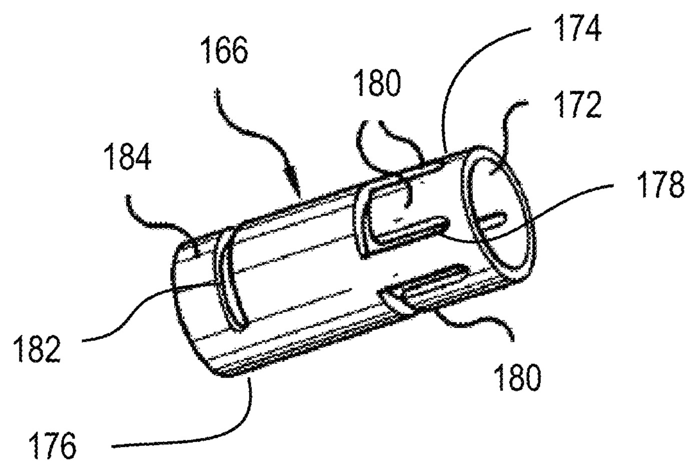


Fig. 3F



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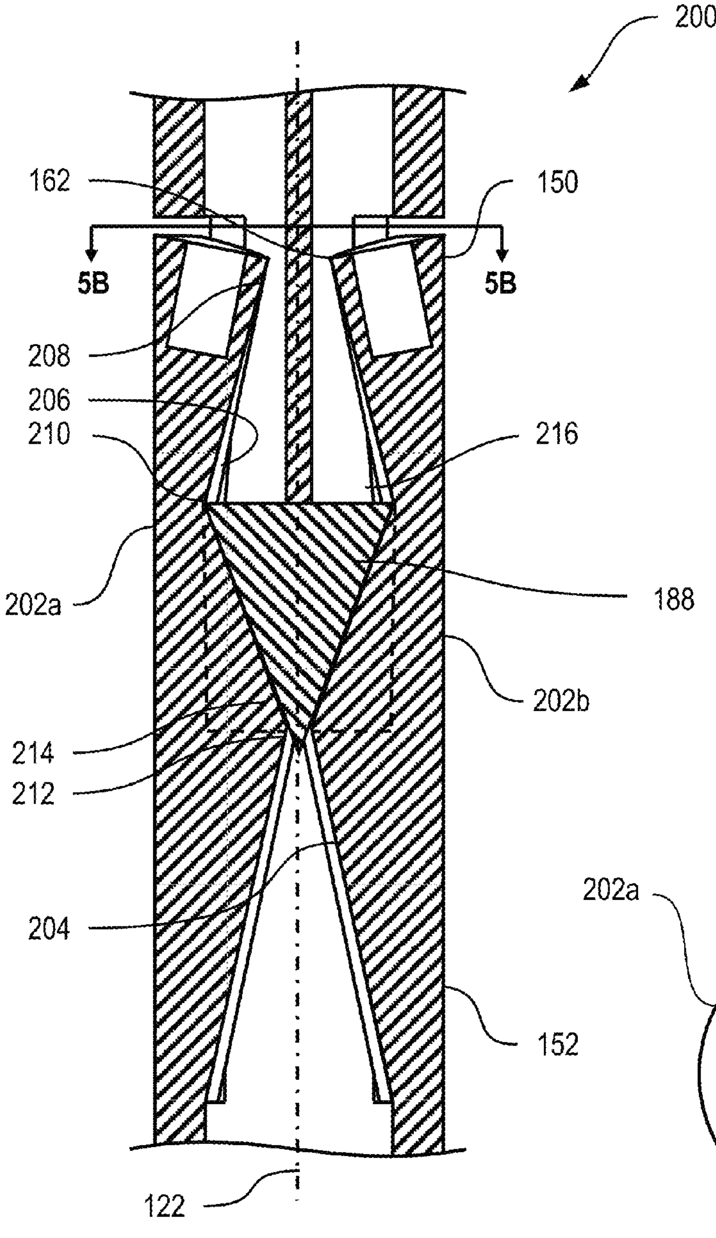

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Fig. 5A

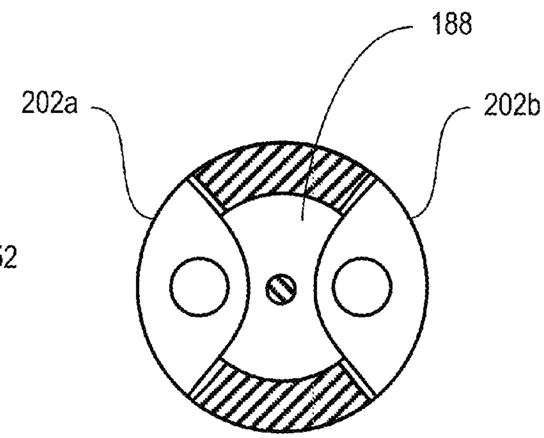

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Fig. 5B

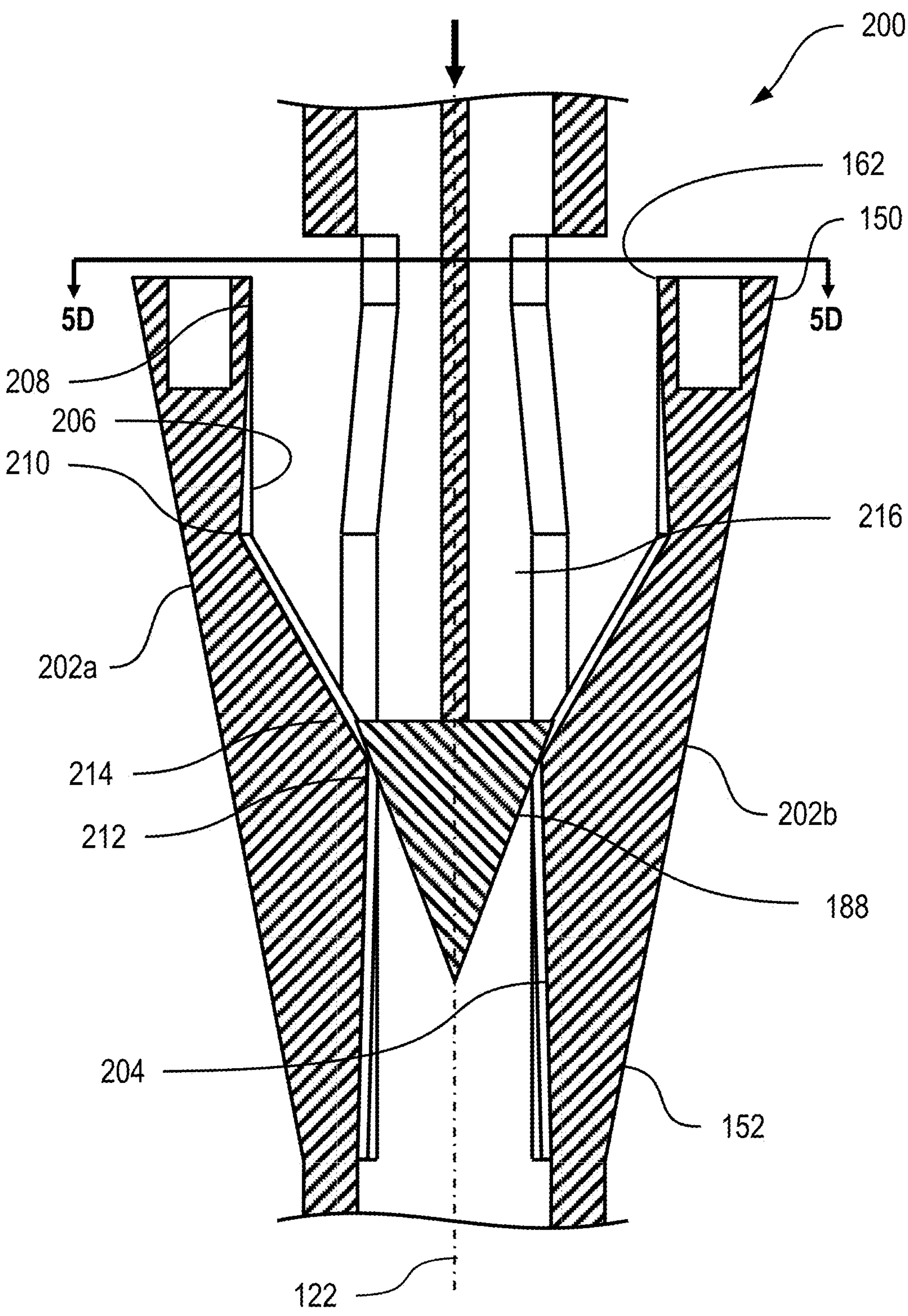
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Fig. 5C

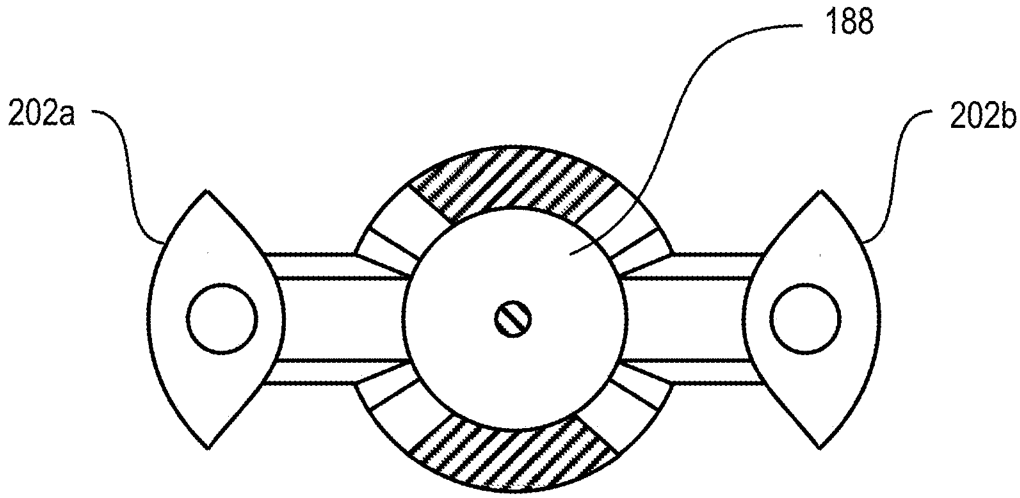

Fig. 5D

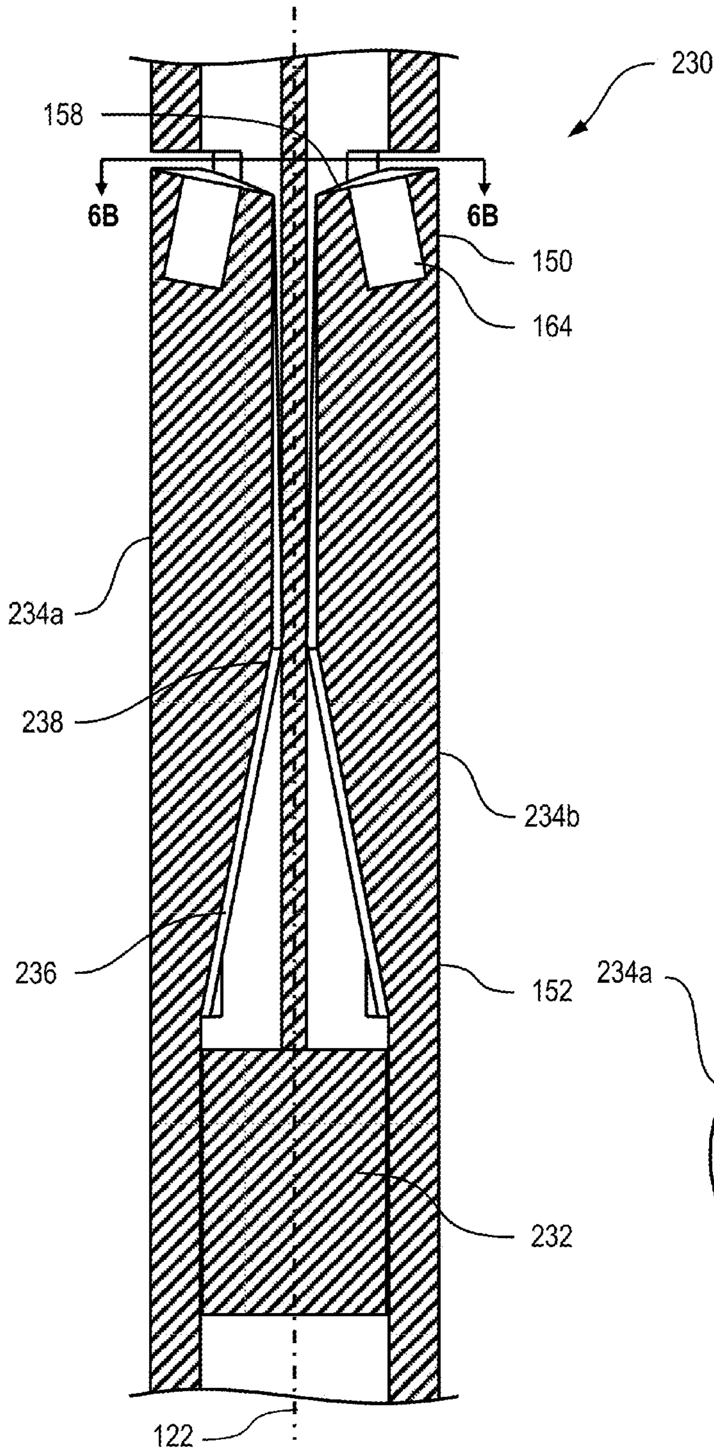
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Fig. 6A

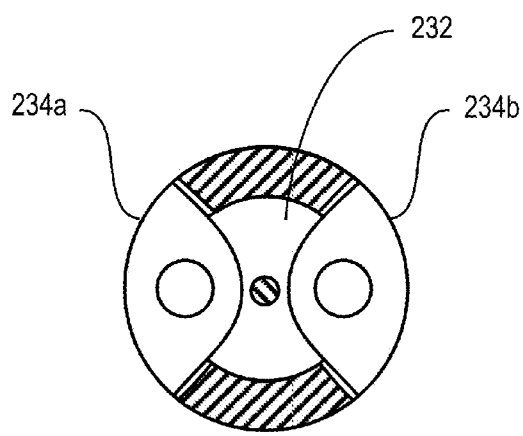
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Fig. 6B

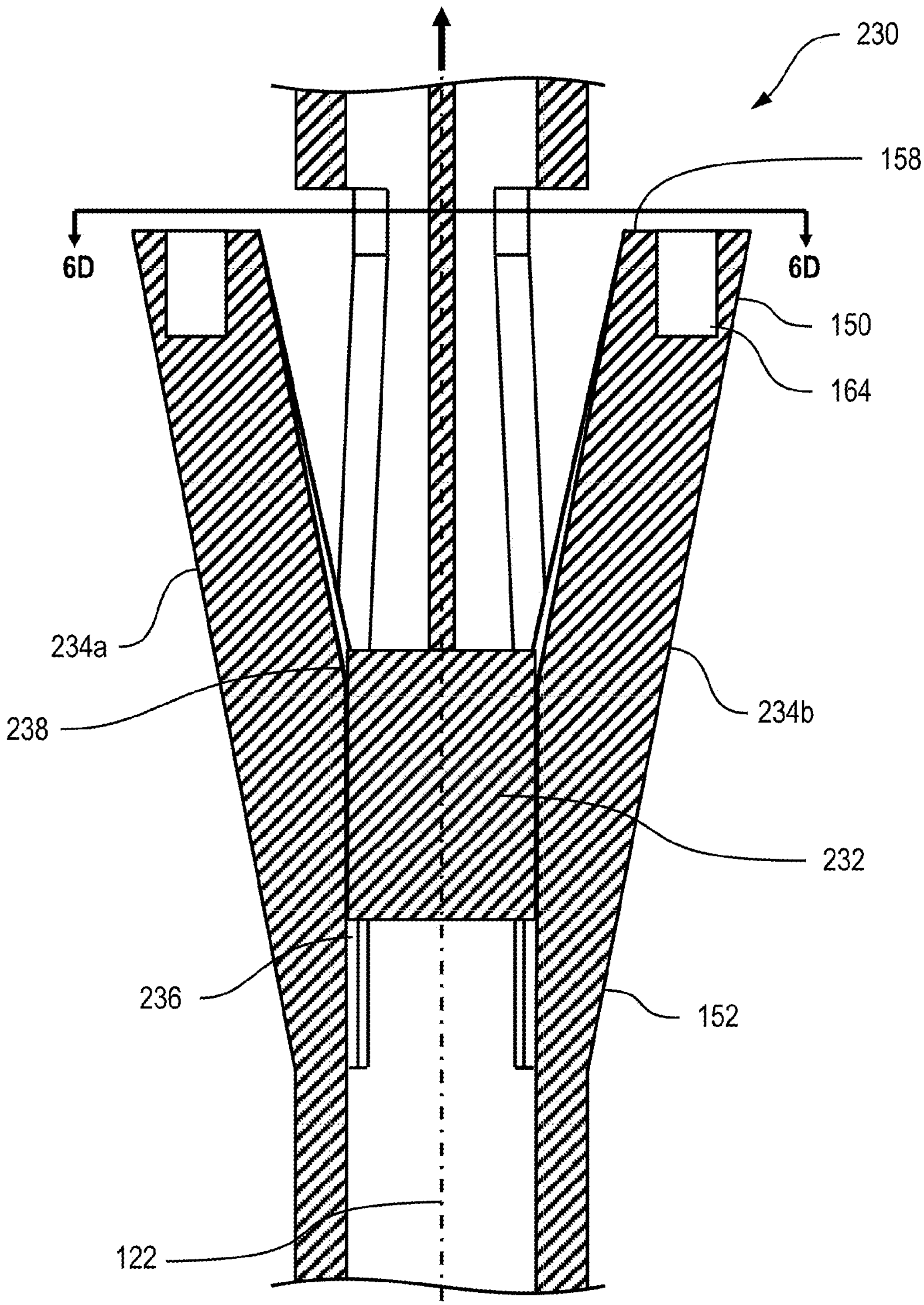

Fig. 6C

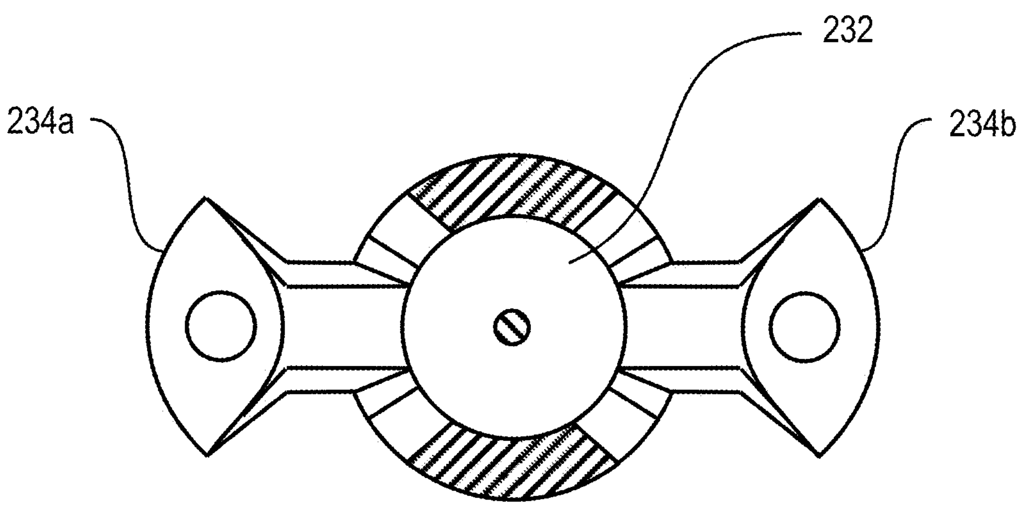

Fig. 6D

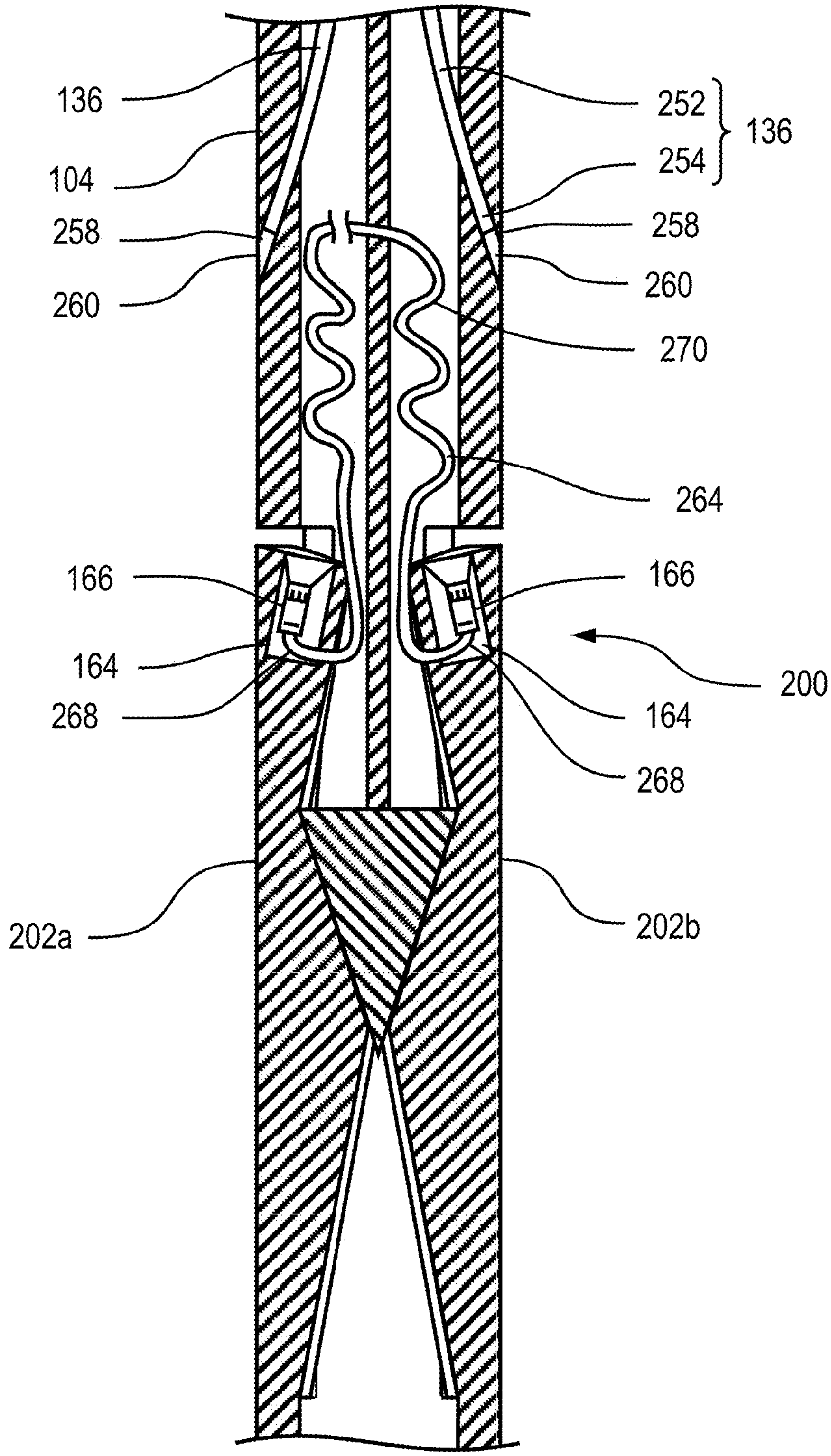
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Fig. 7A

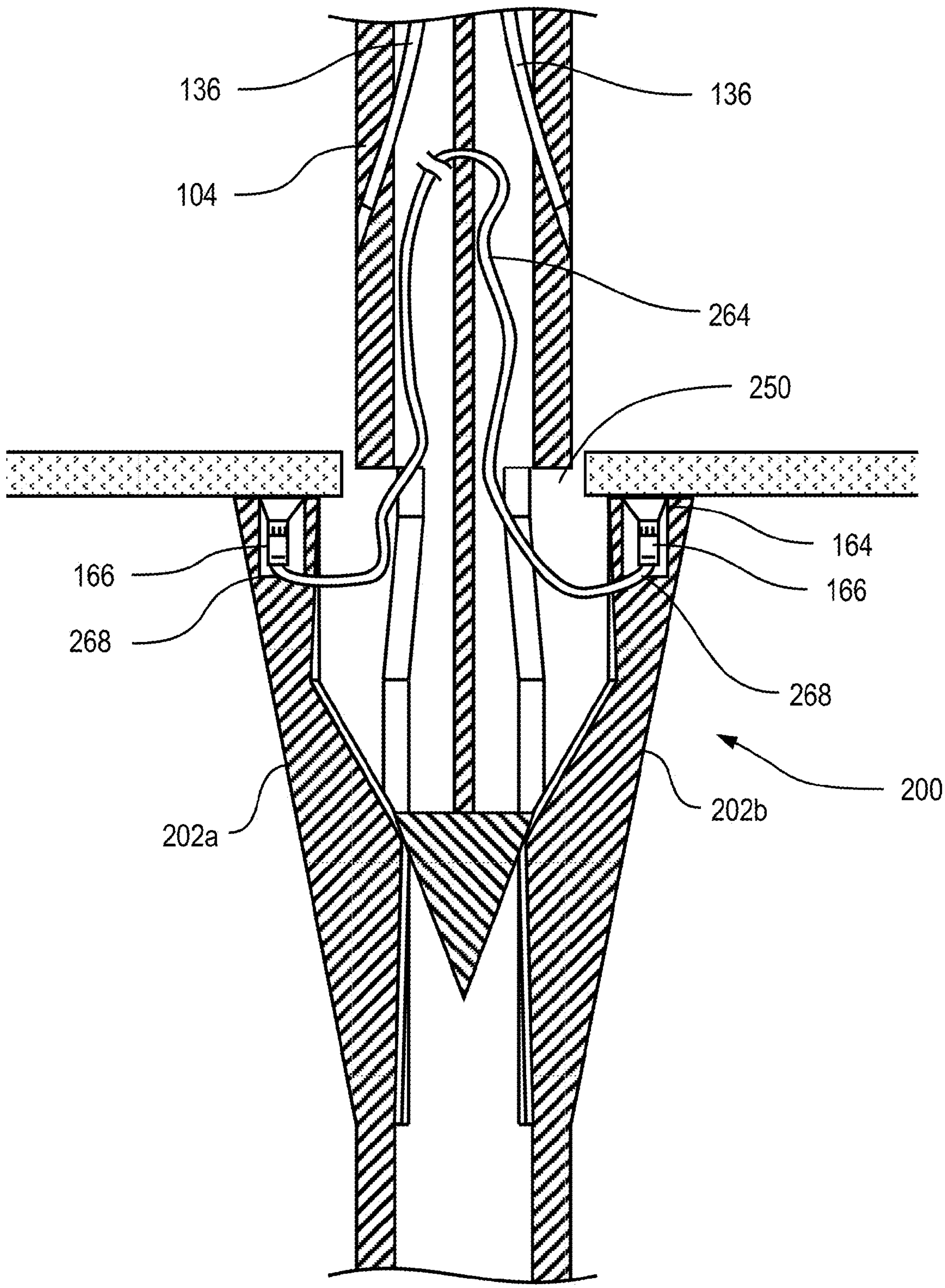

Fig. 7B

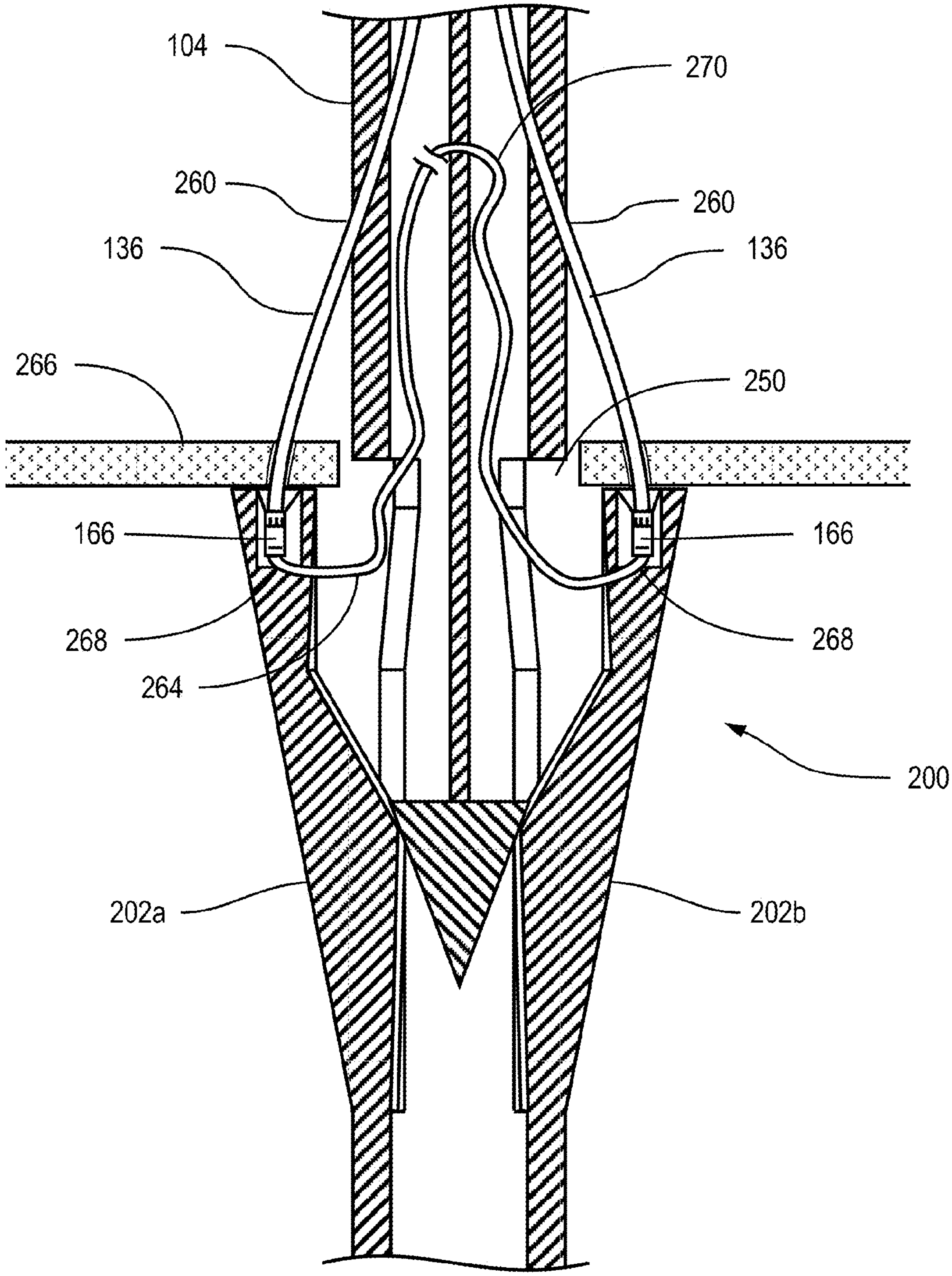
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Fig. 7C

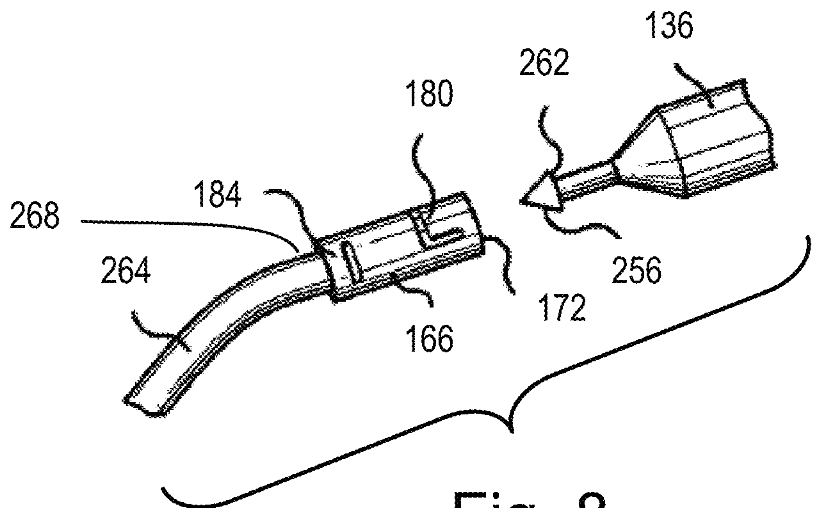


Fig. 8

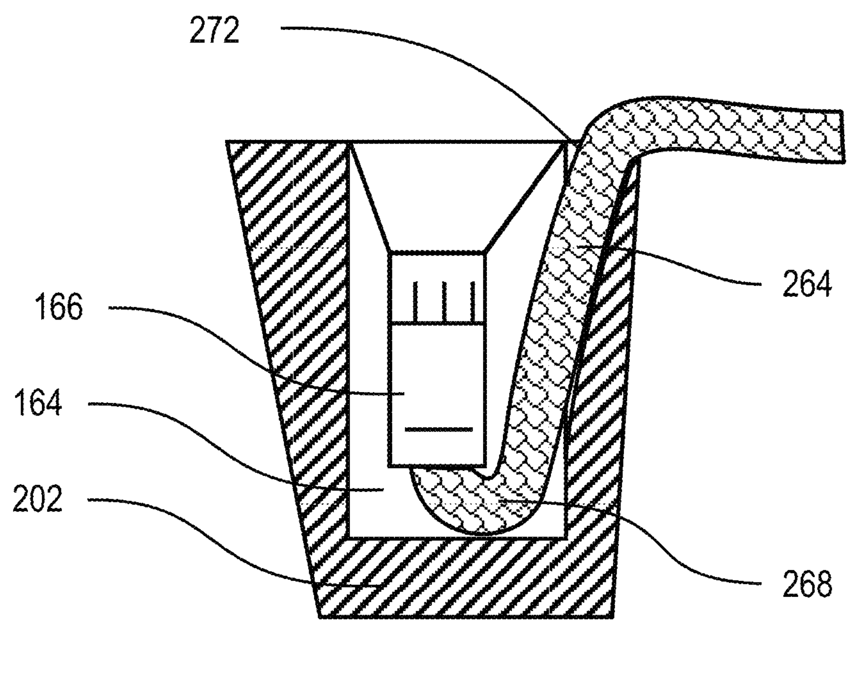
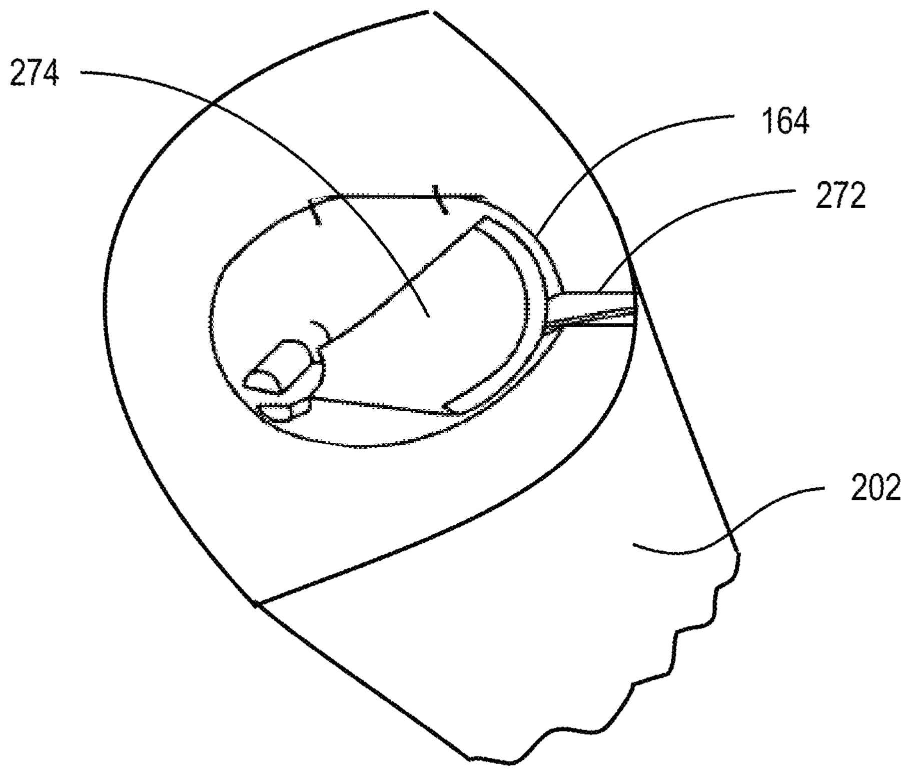


Fig. 9



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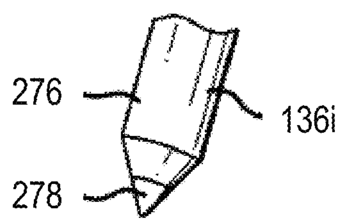
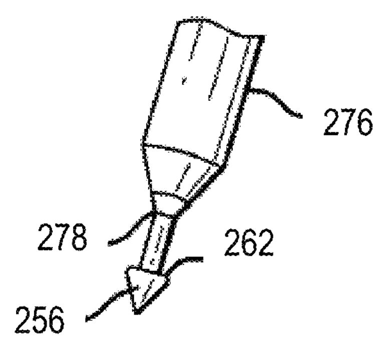


Fig. 10B



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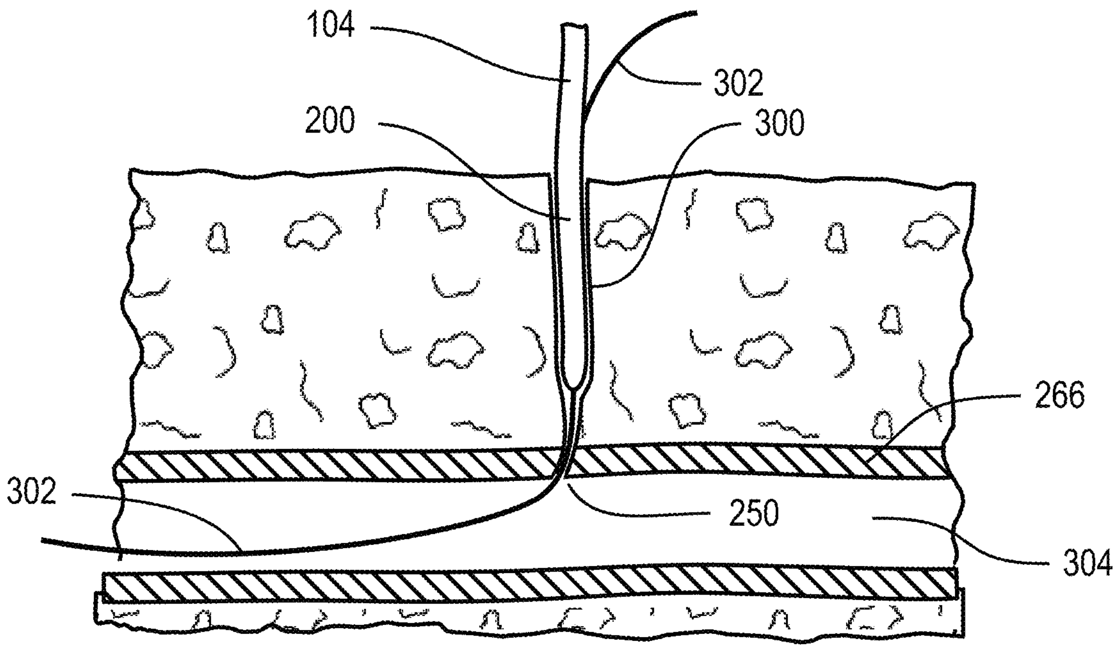


Fig. 11A

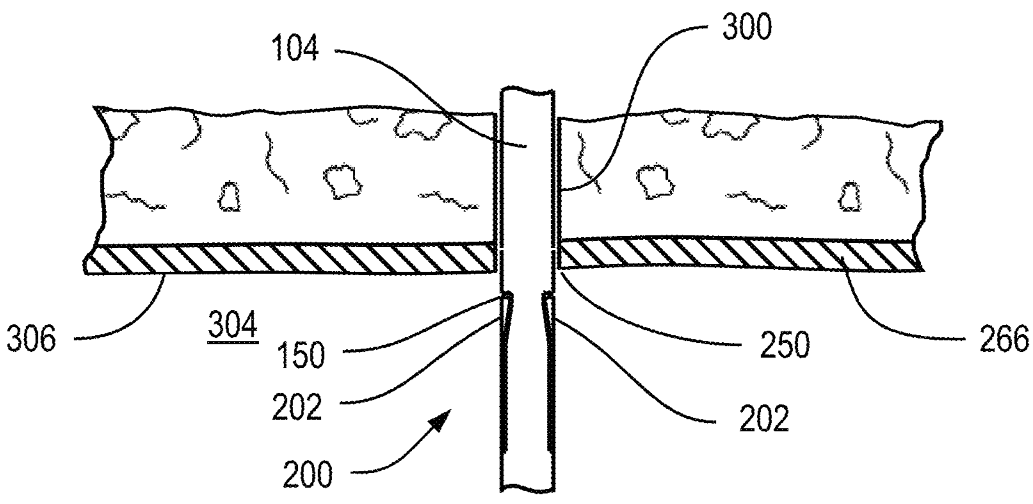
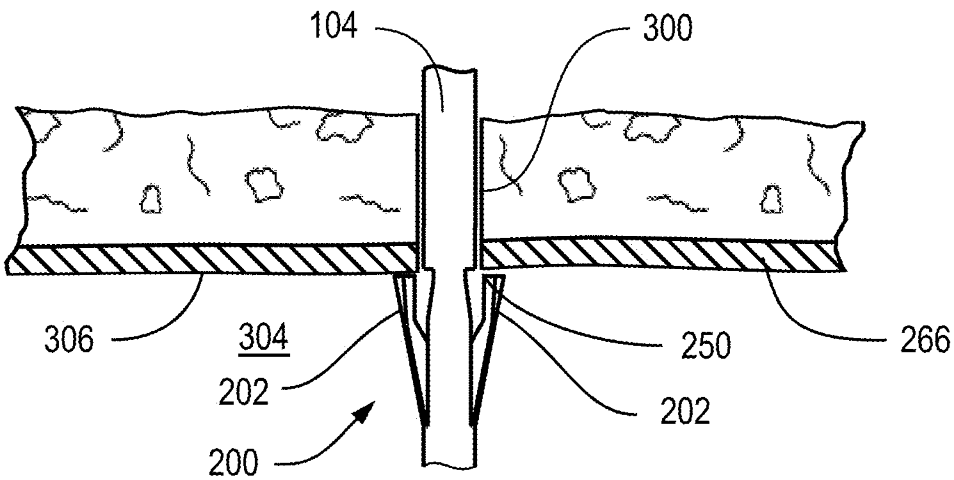


Fig. 11B



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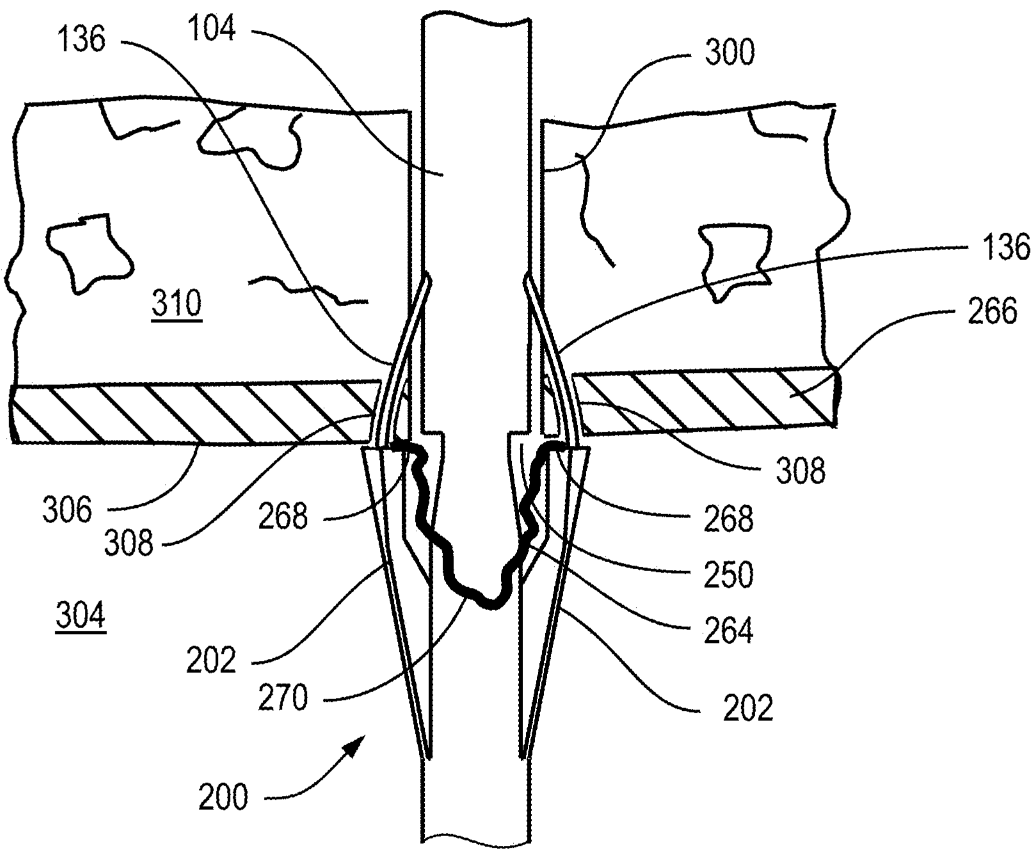

Fig. 11D

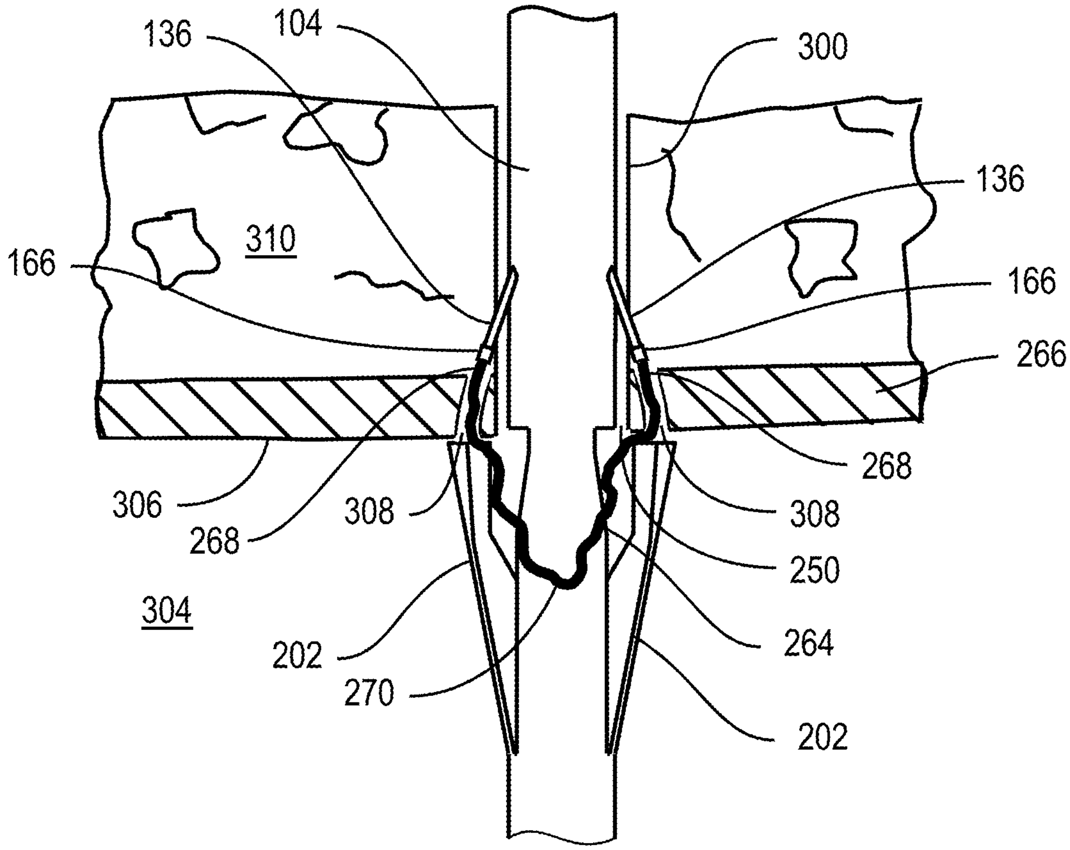
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Fig. 11E

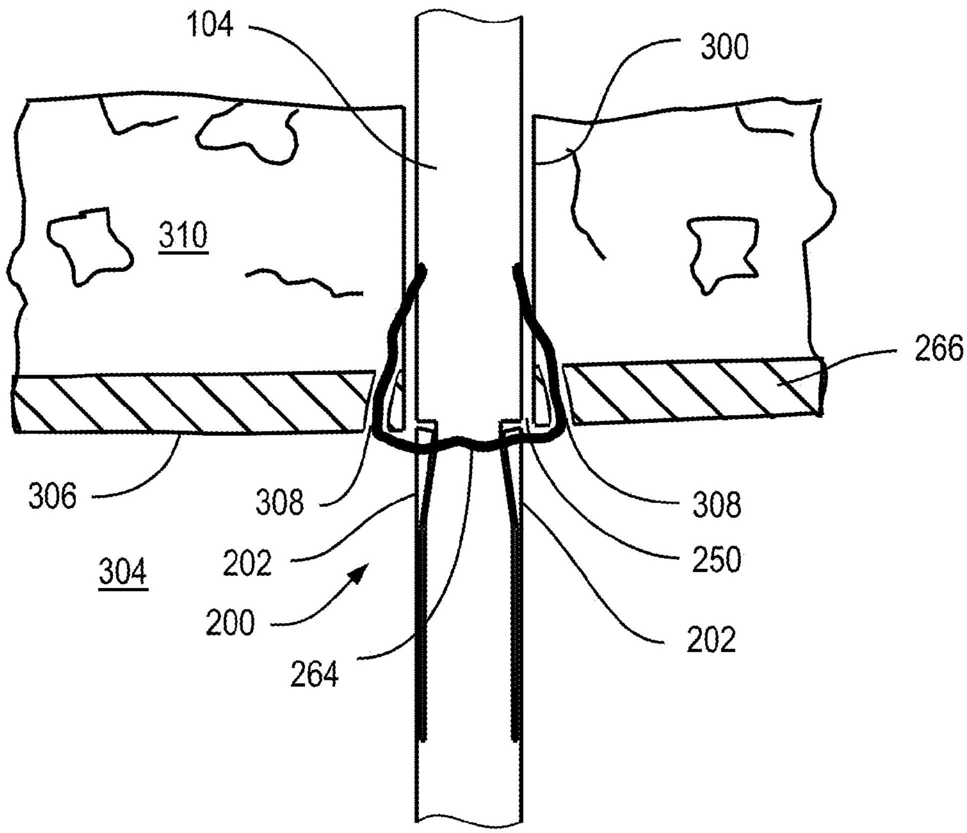

Fig. 11F

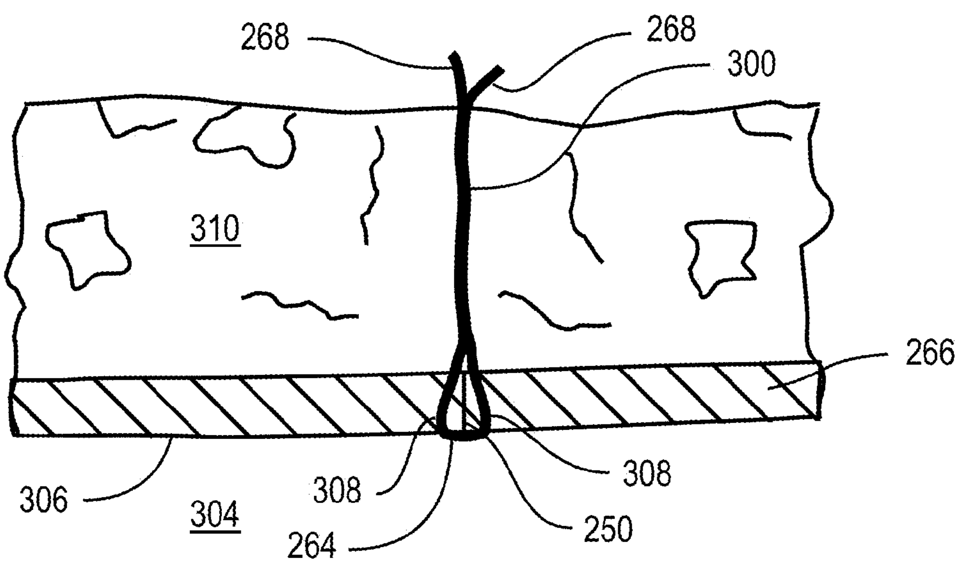

Fig. 11G

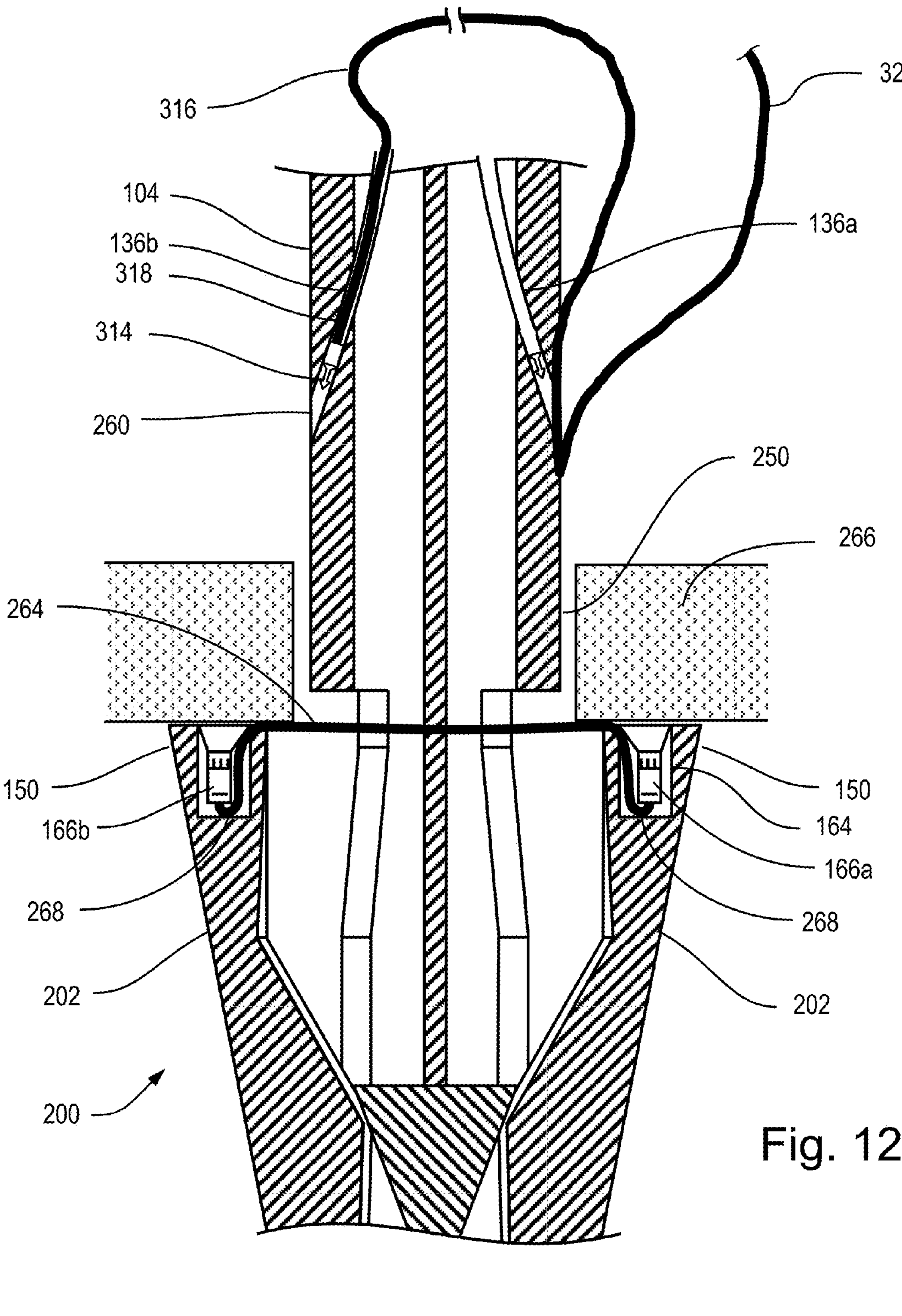
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Fig. 12A

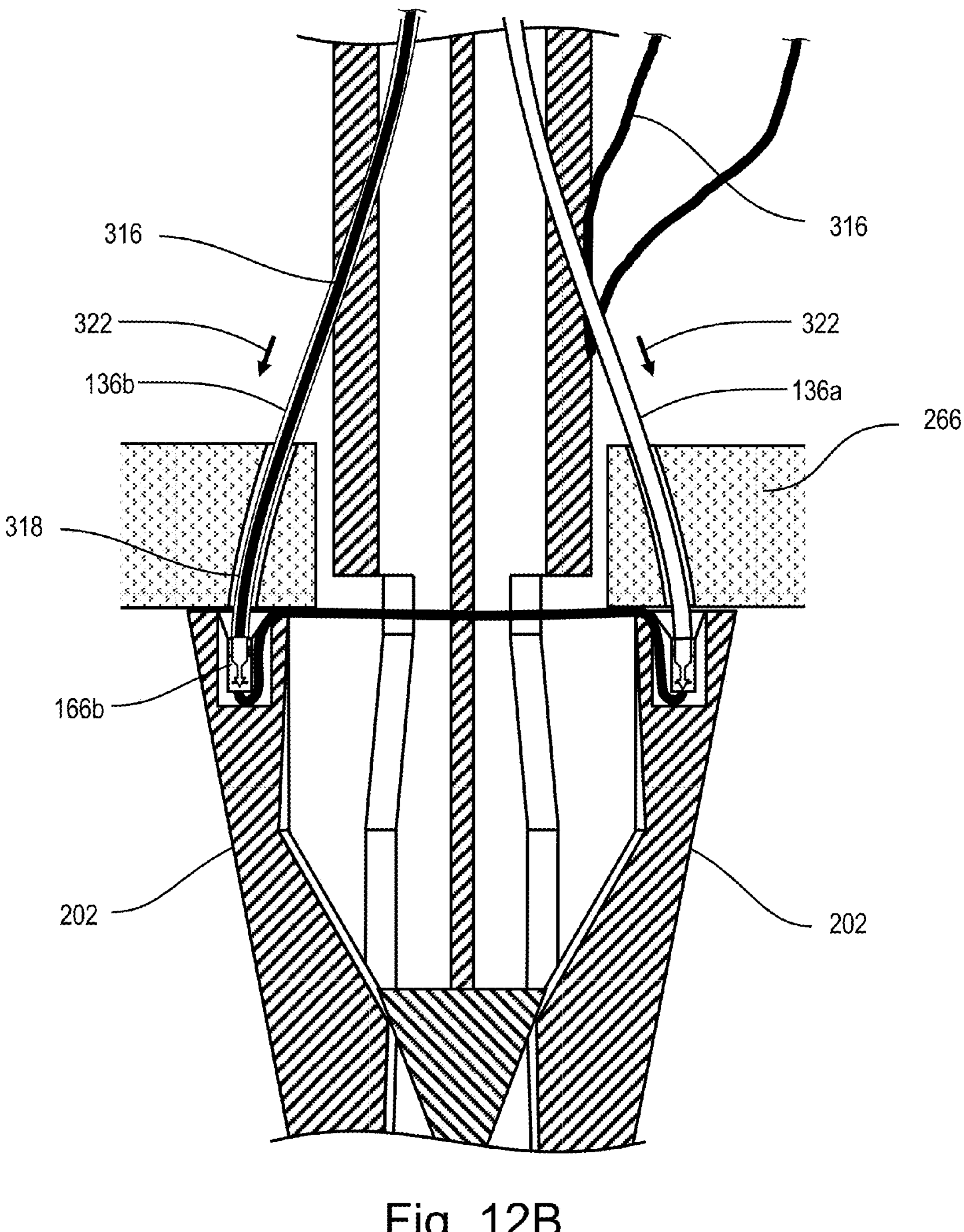

Fig. 12B

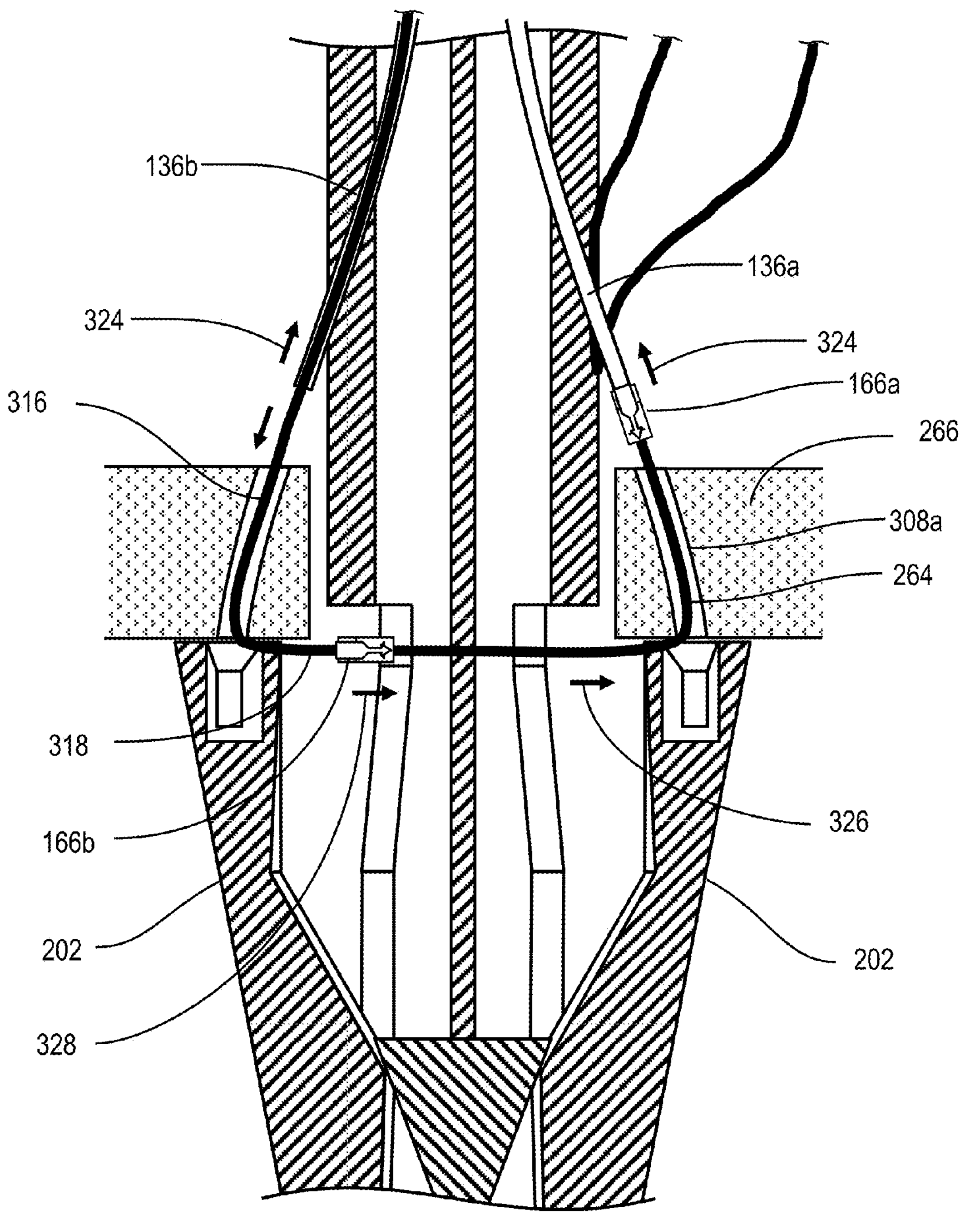
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Fig. 12C

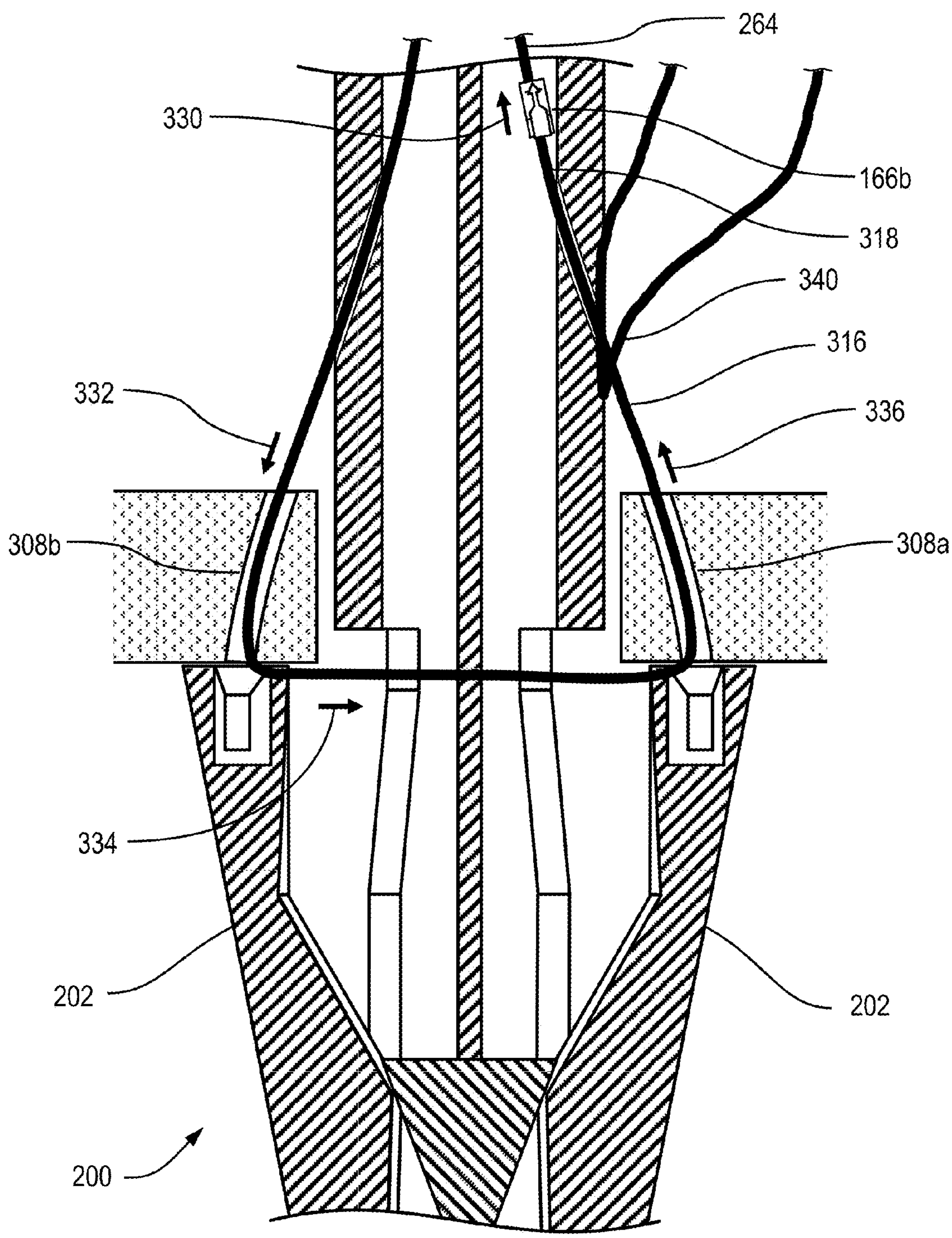


Fig. 12D

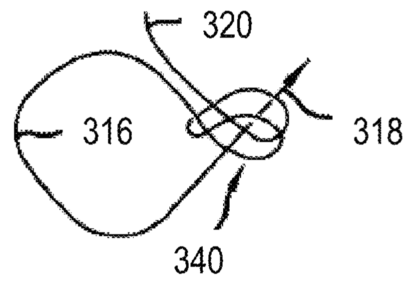


Fig. 13A

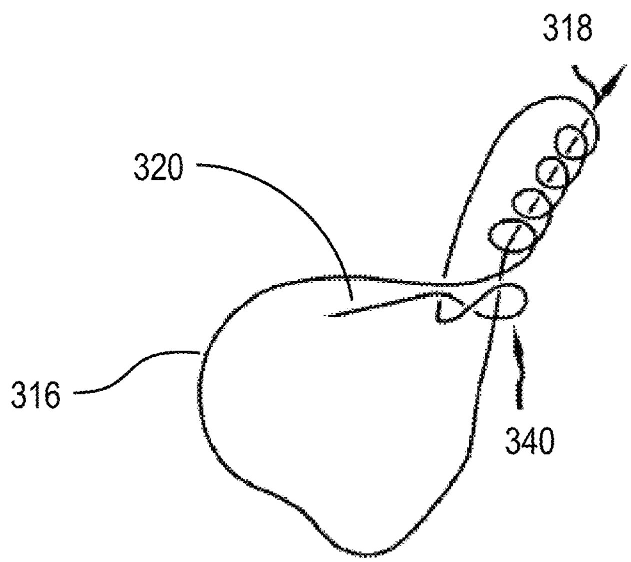
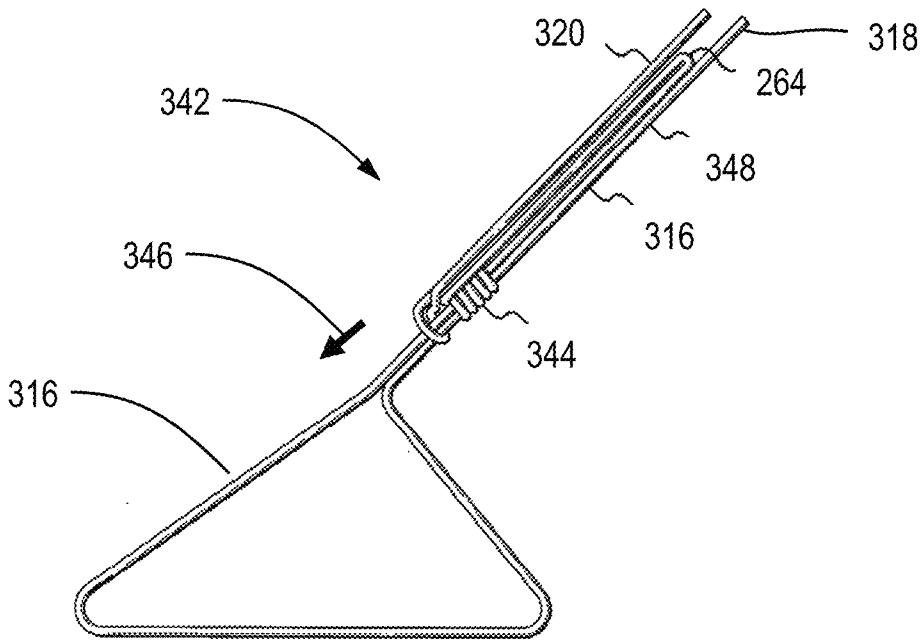


Fig. 13B



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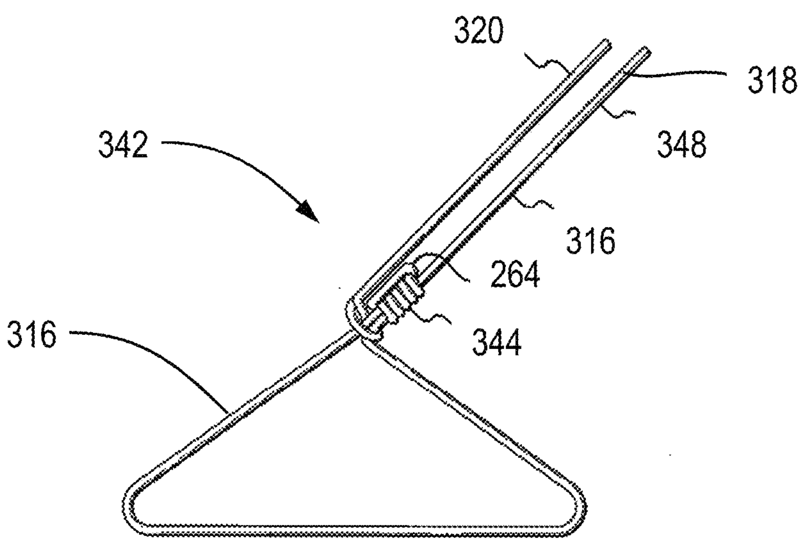
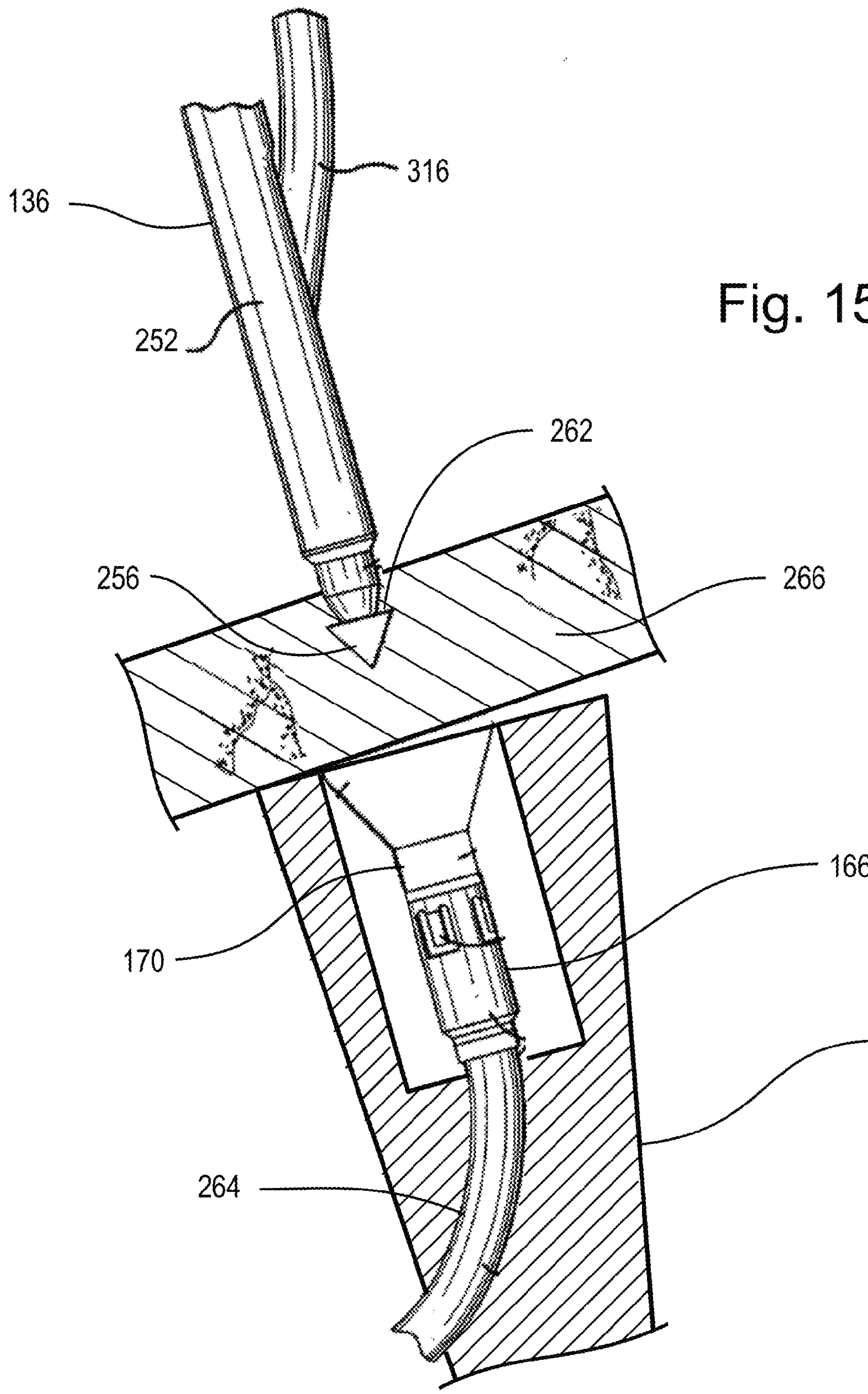


Fig. 14B



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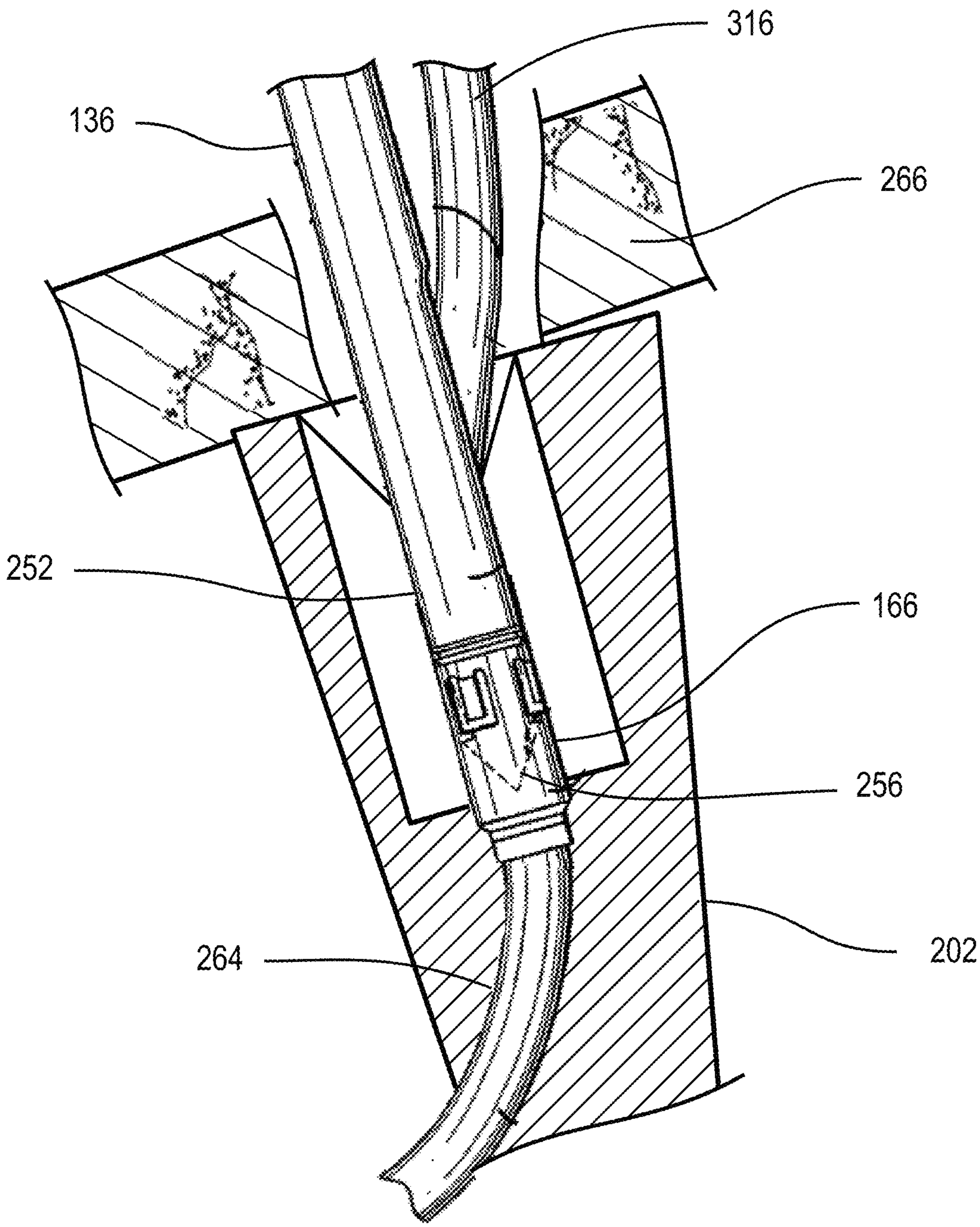


Fig. 15B

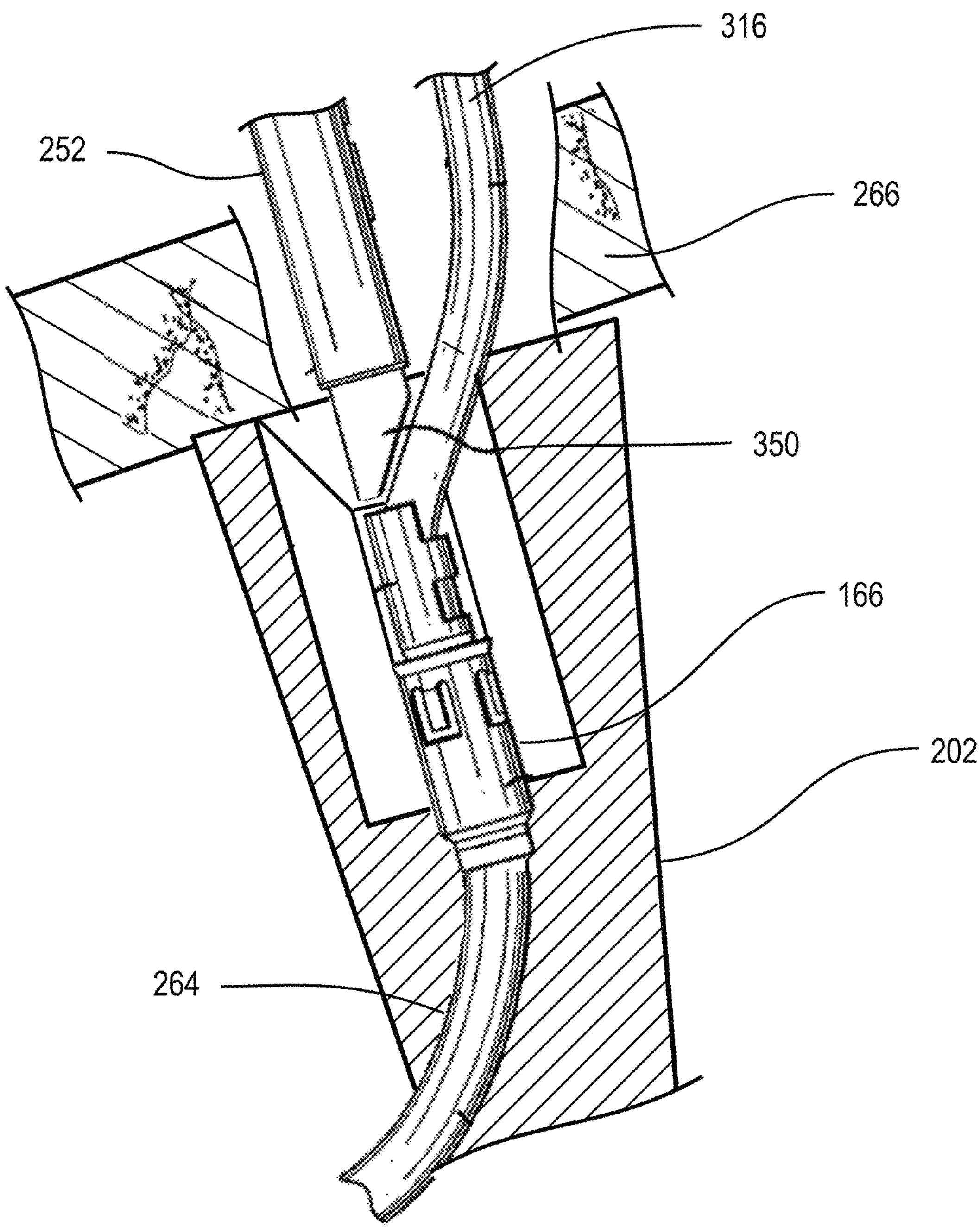


Fig. 15C

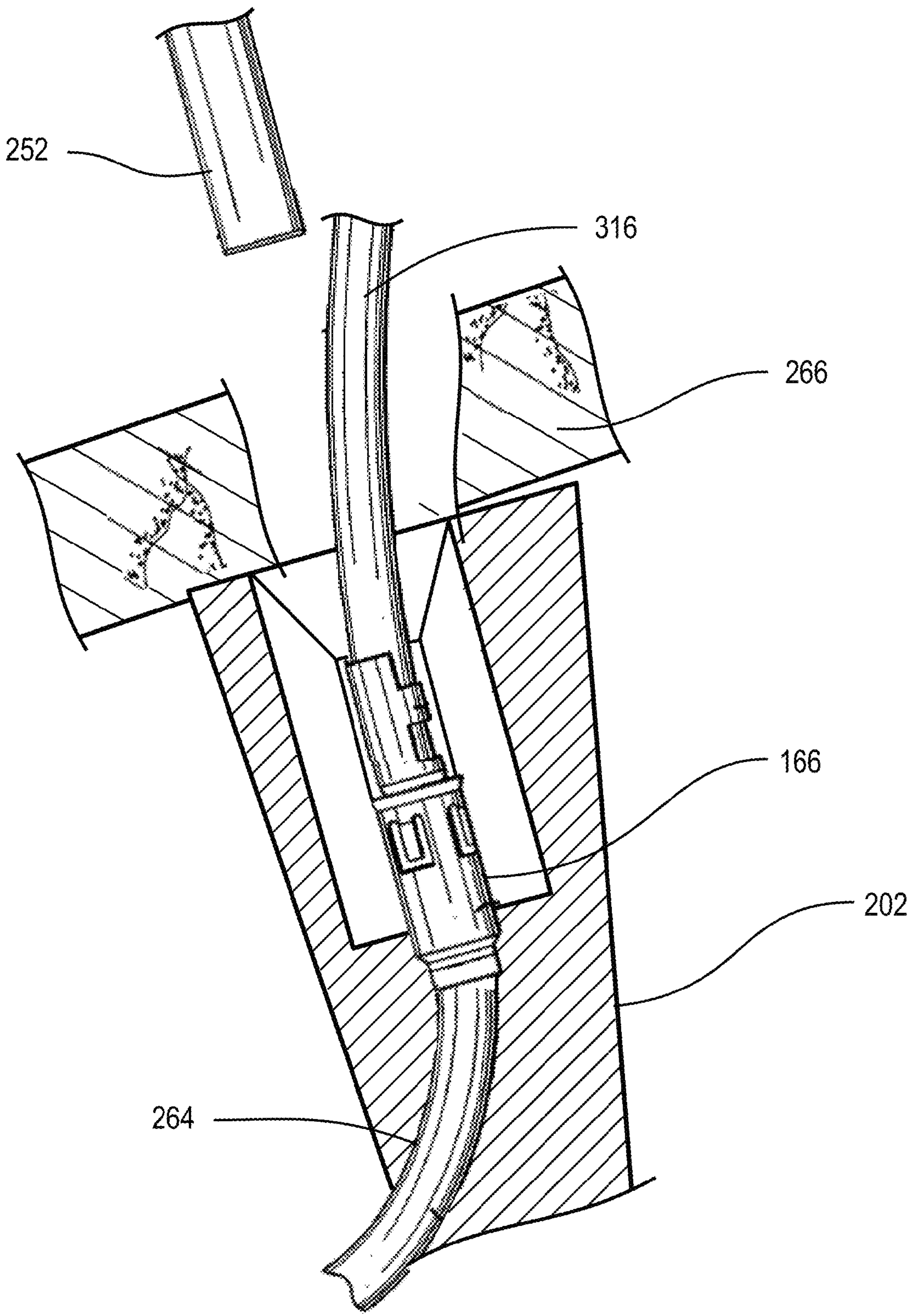


Fig. 15D

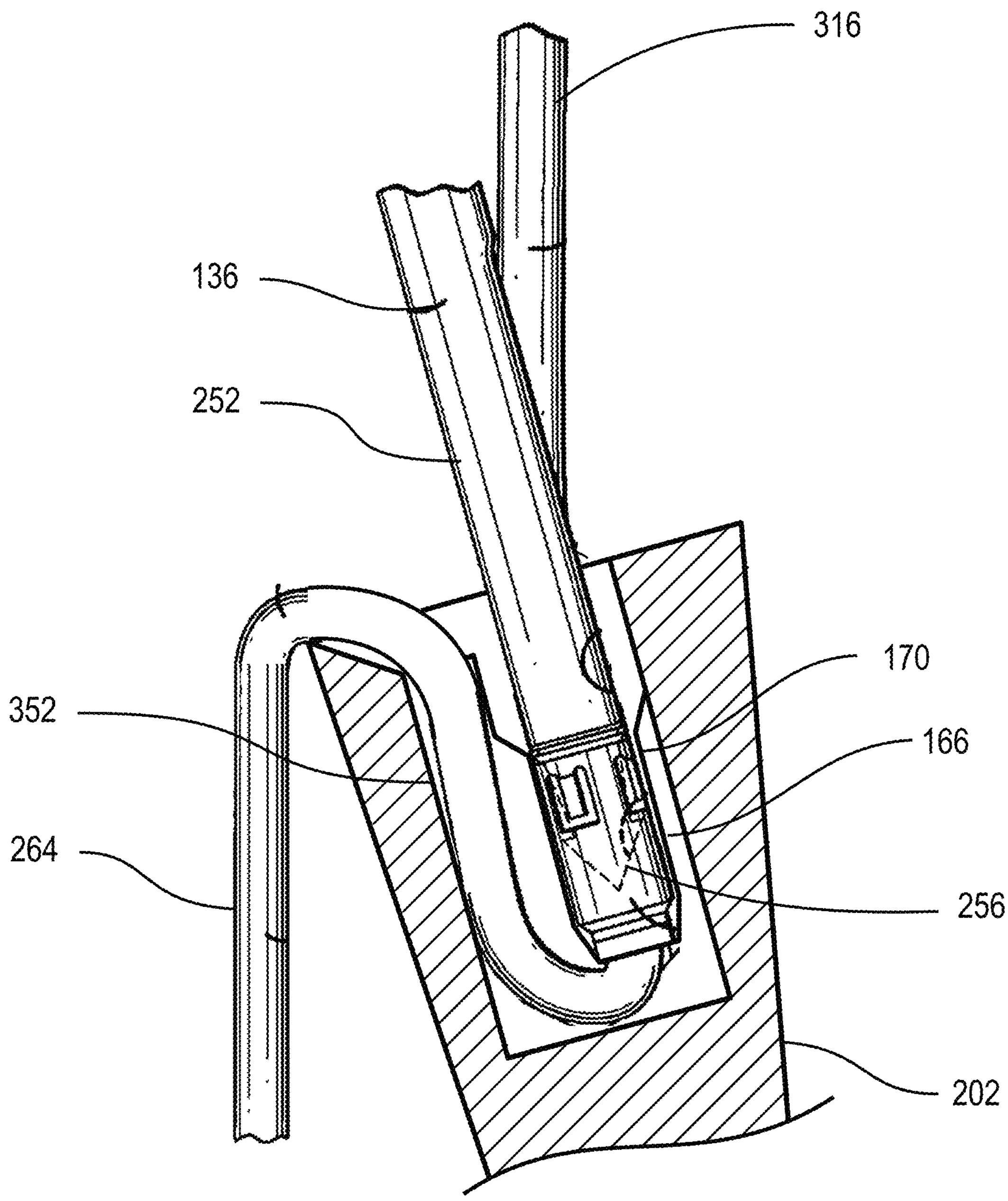


Fig. 16A

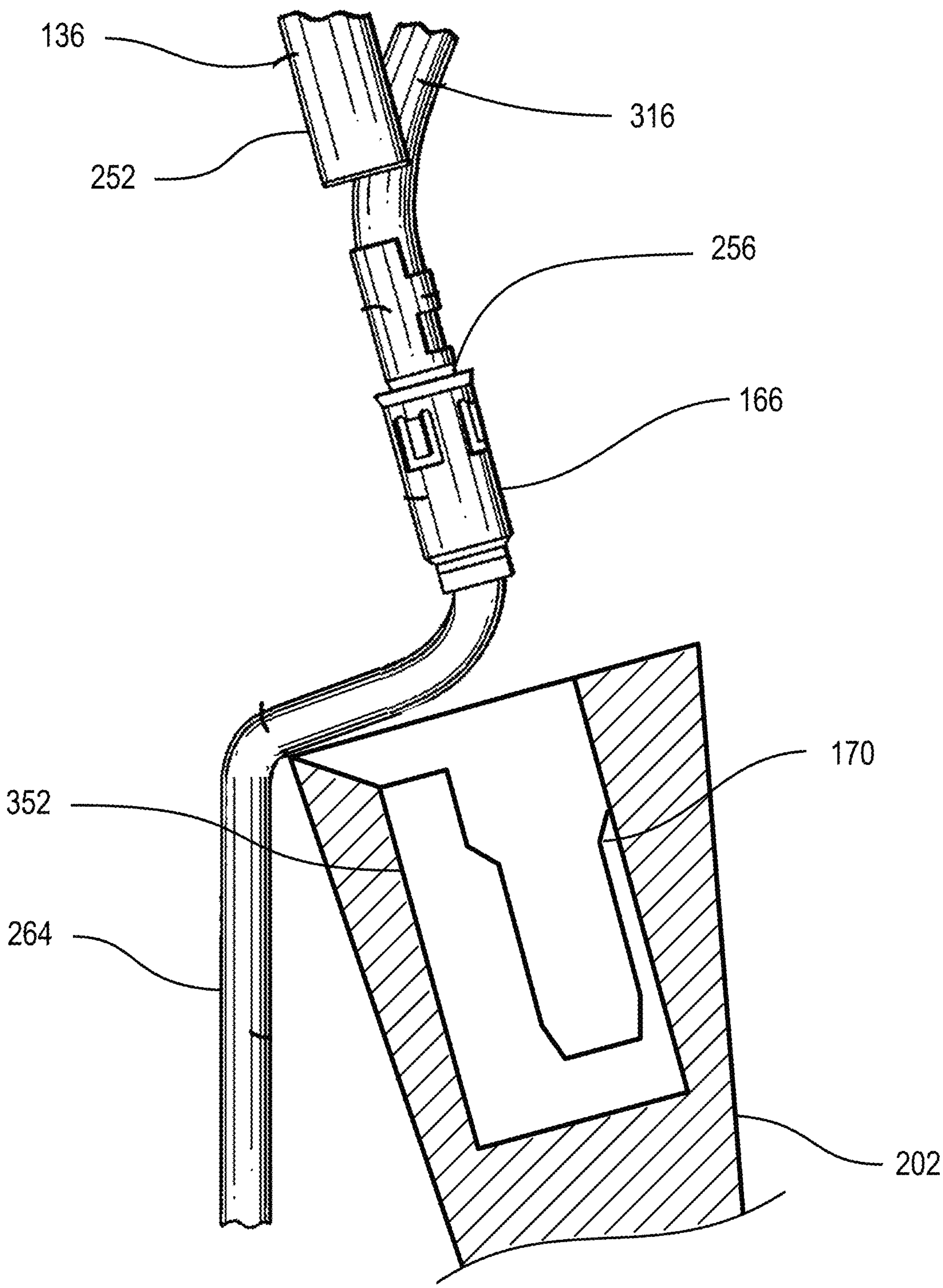


Fig. 16B

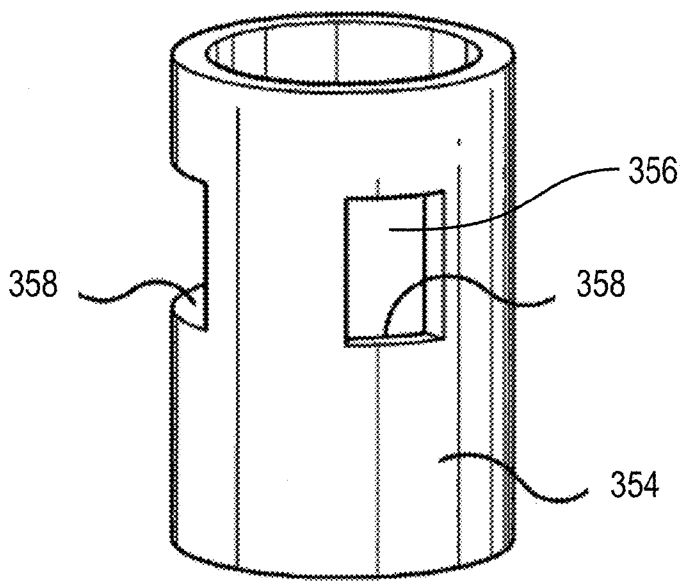


Fig. 17A

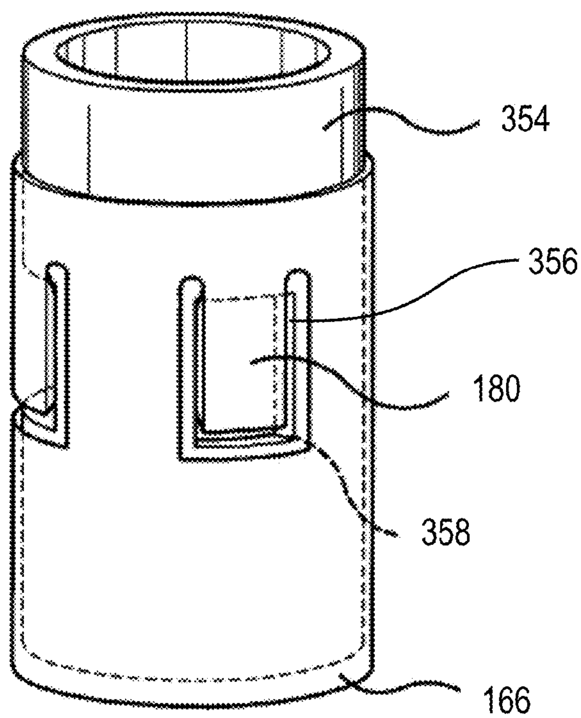
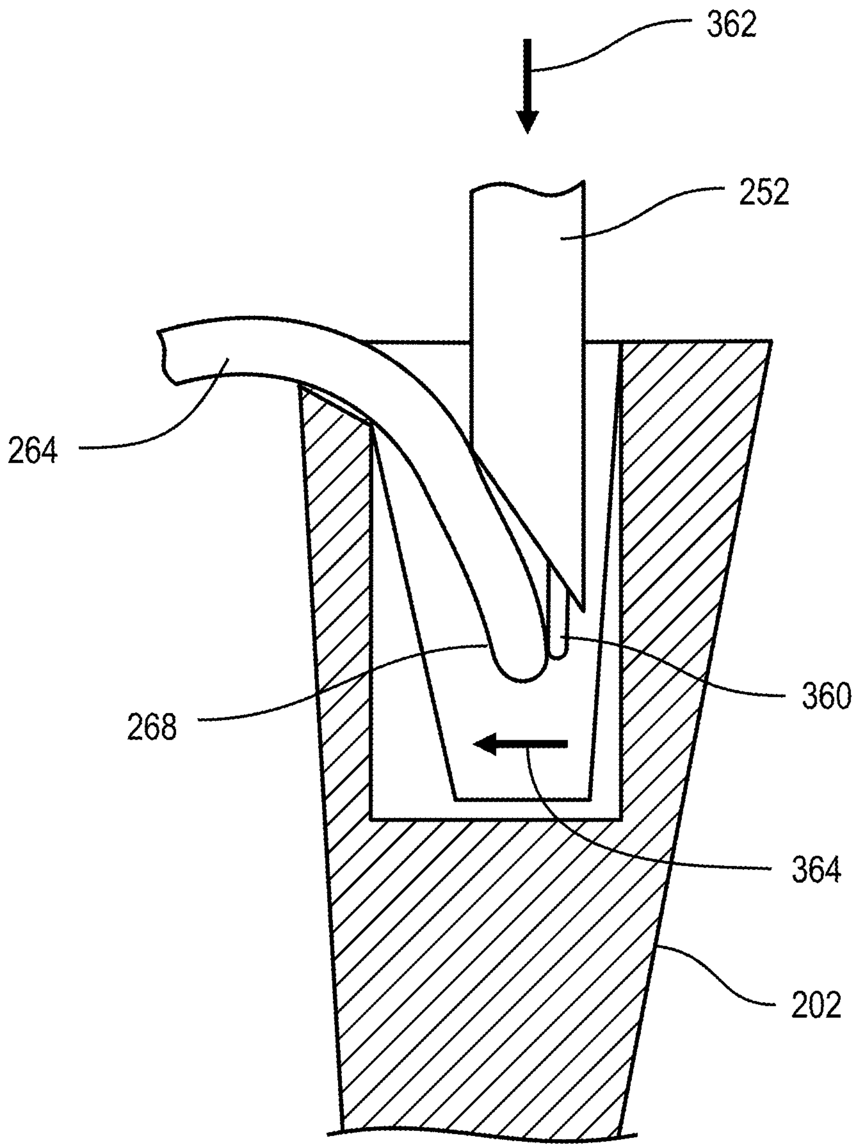


Fig. 17B



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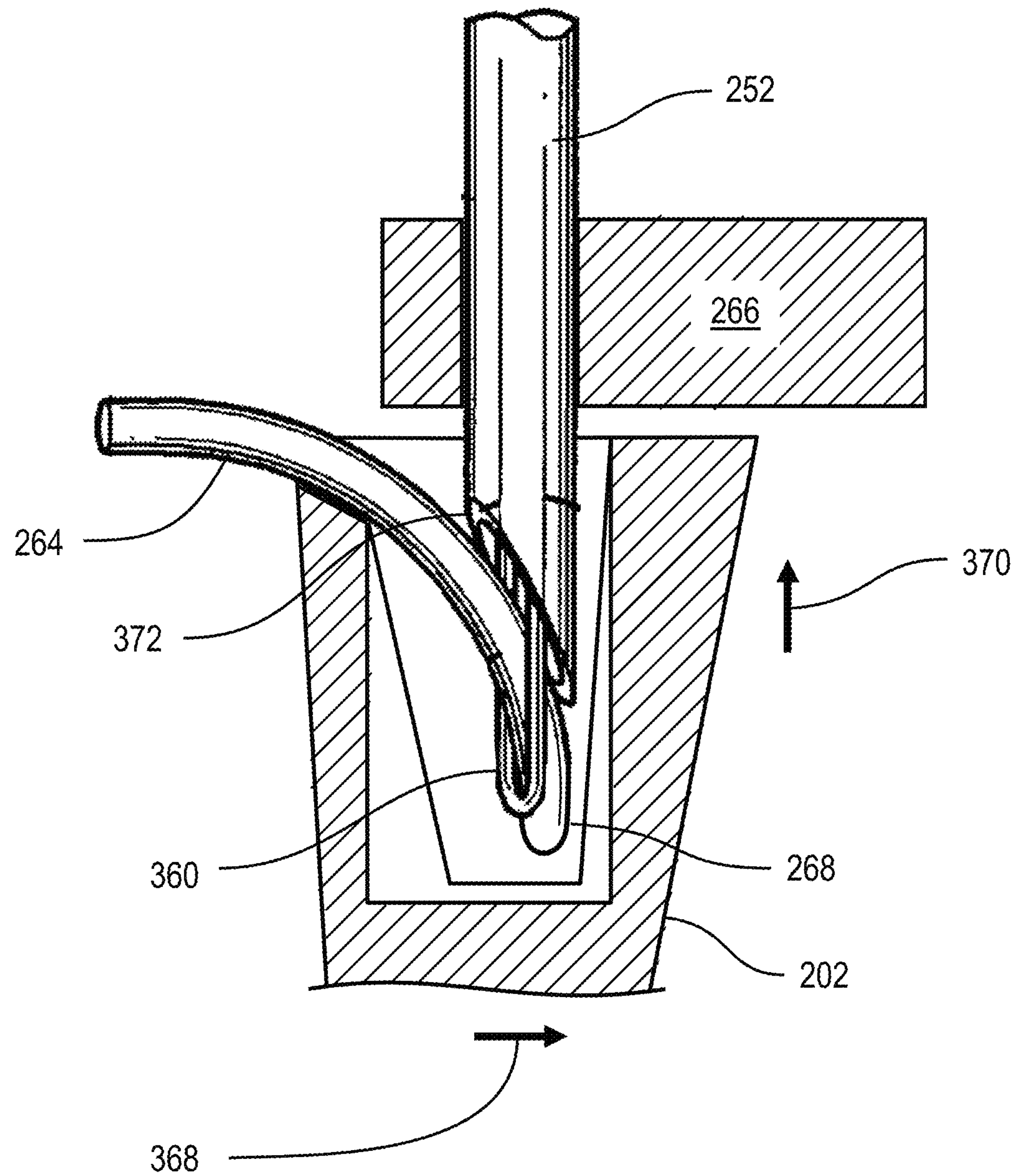

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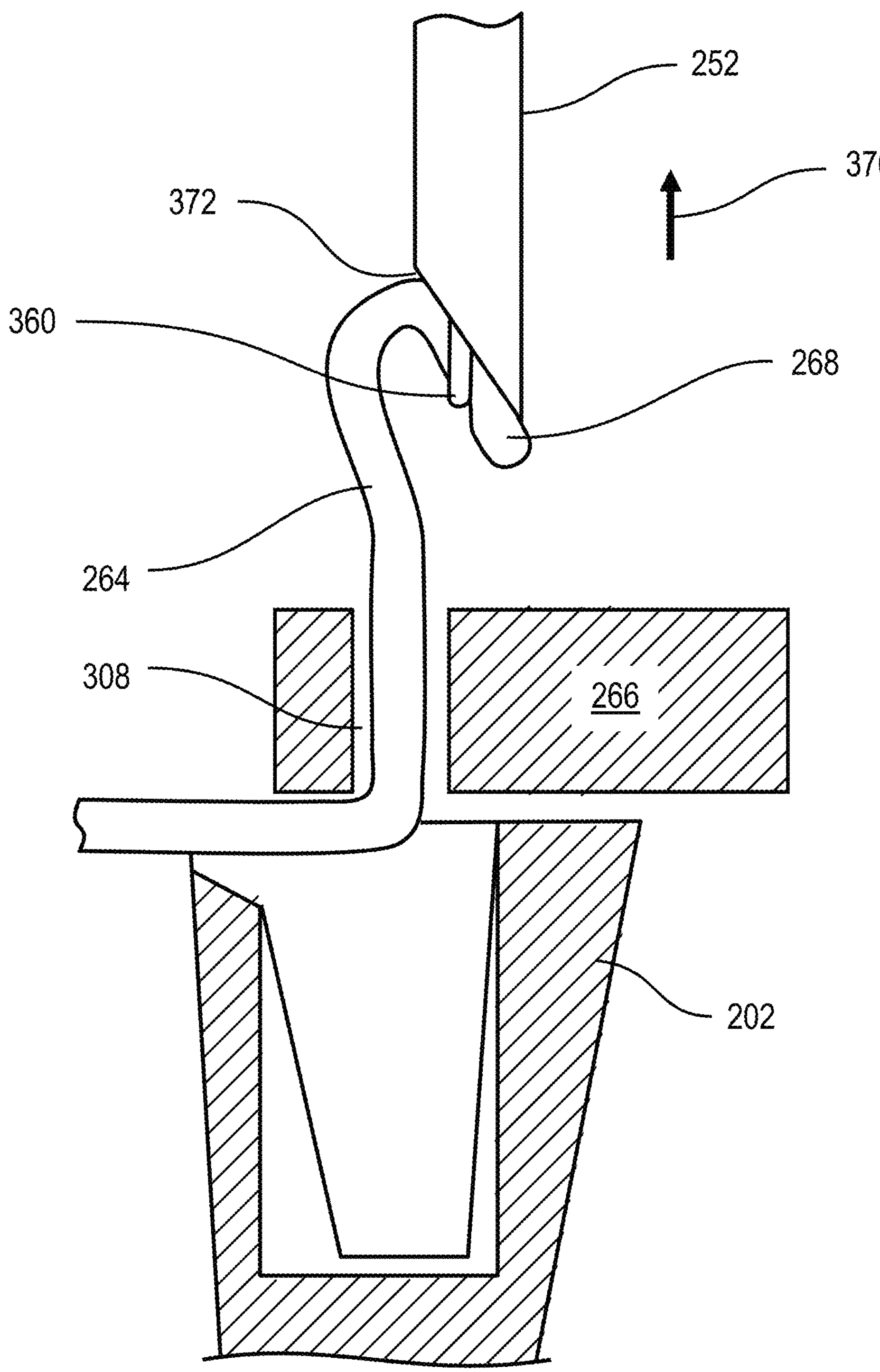

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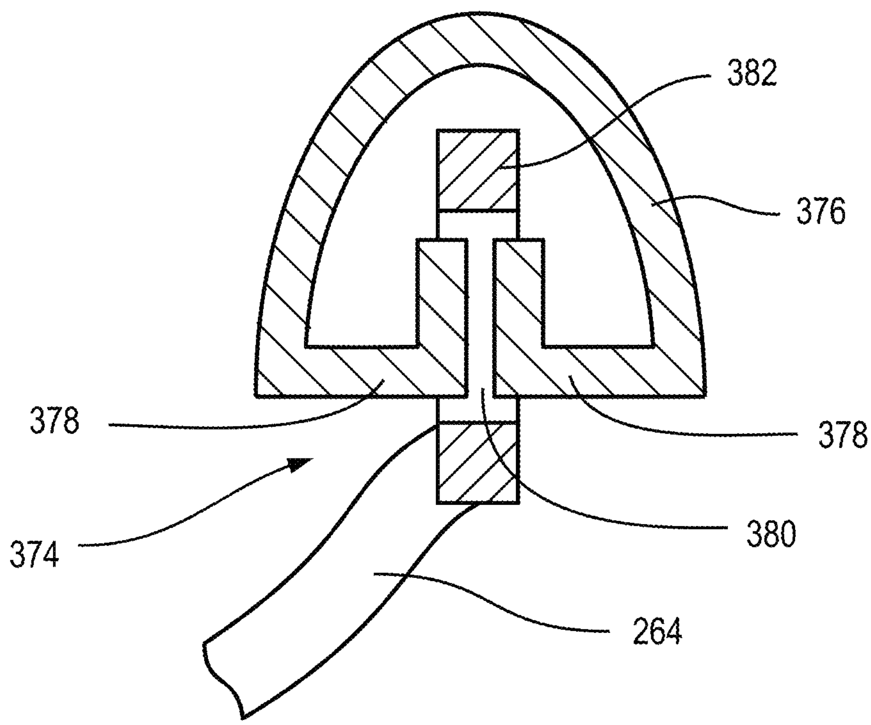

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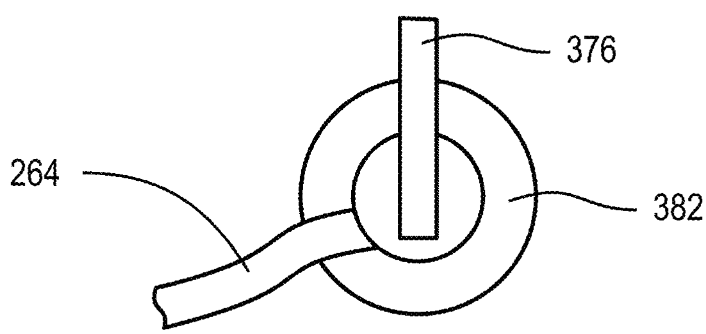

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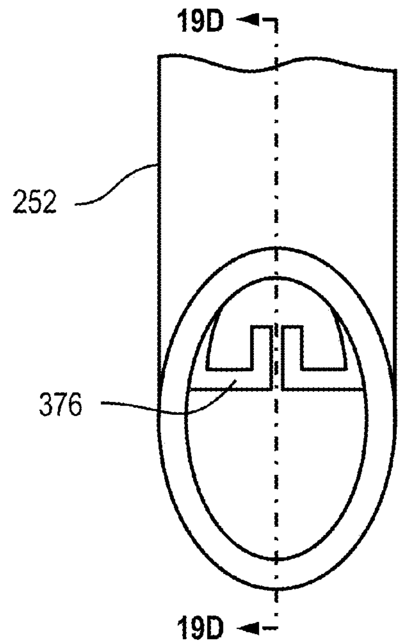
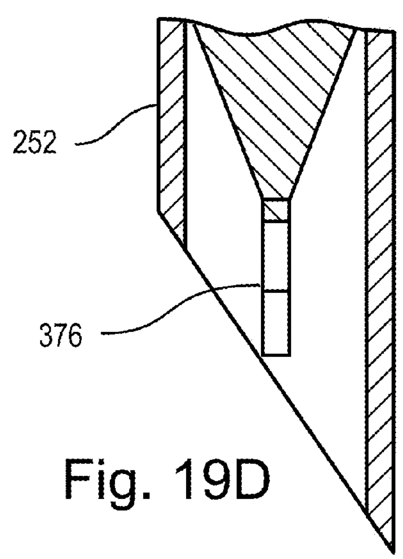


Fig. 19C



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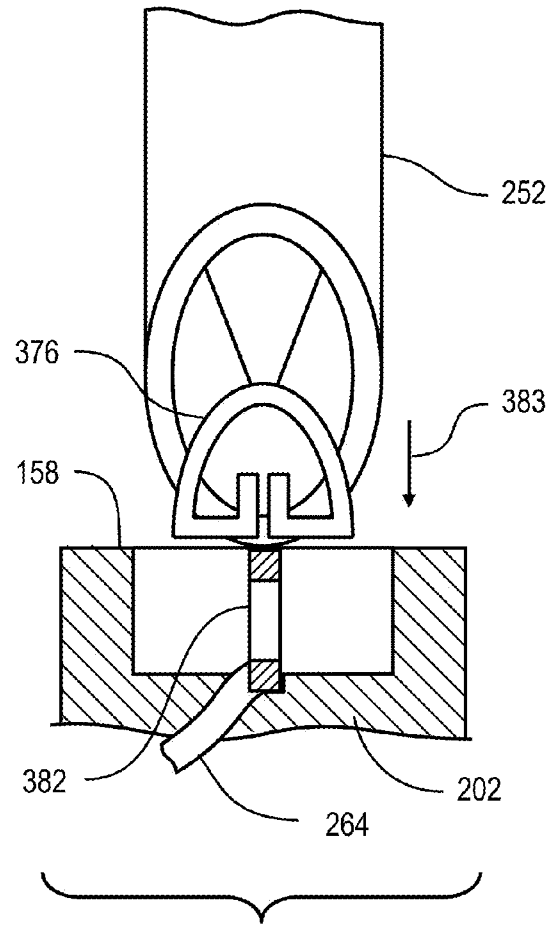
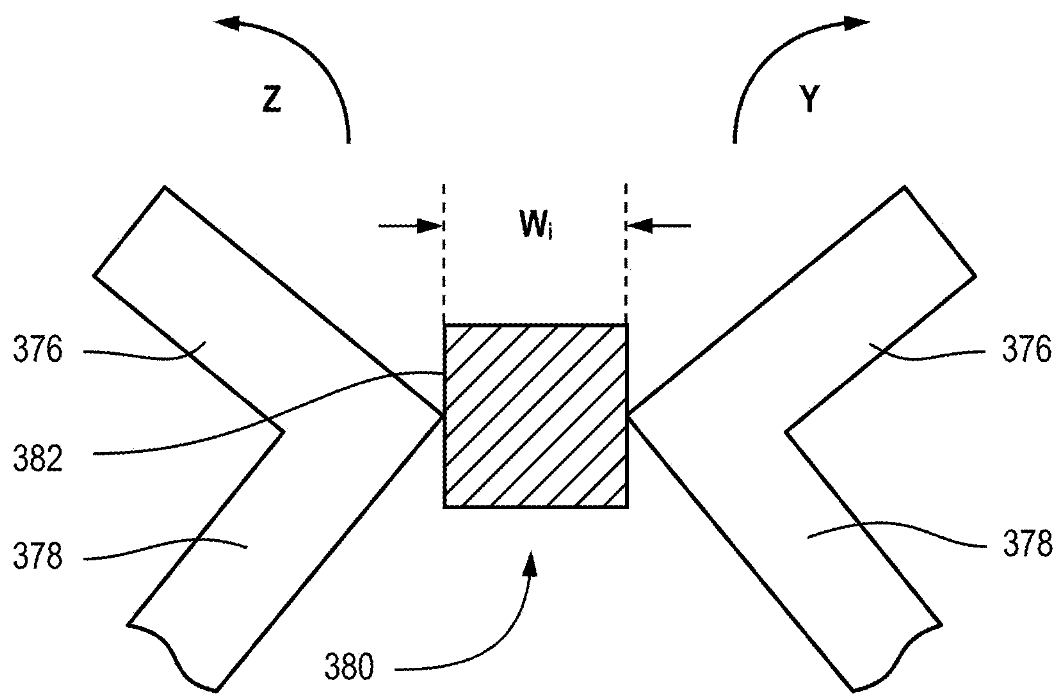


Fig. 19E



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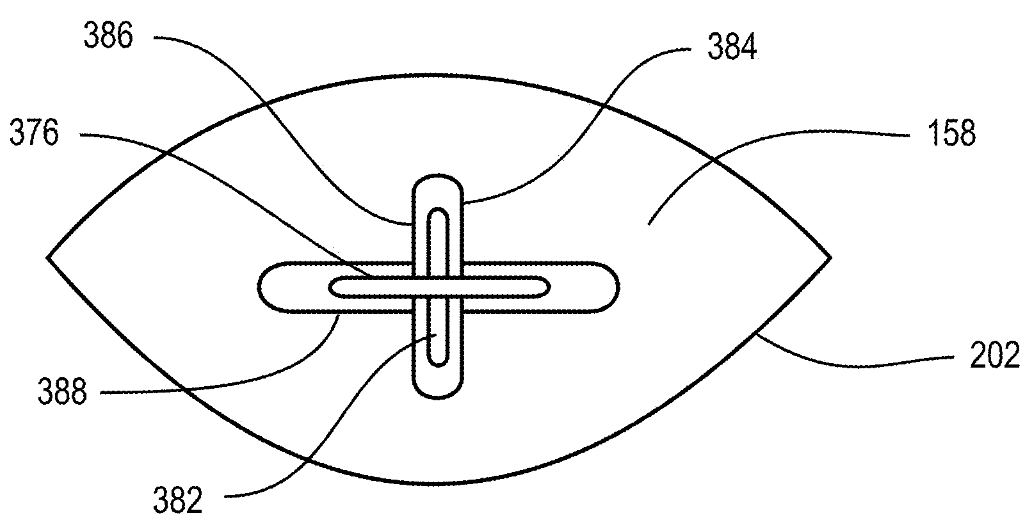


Fig. 19G

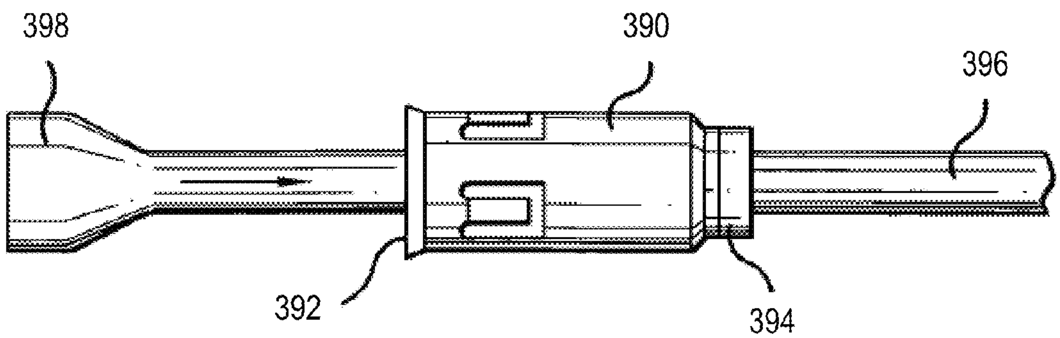
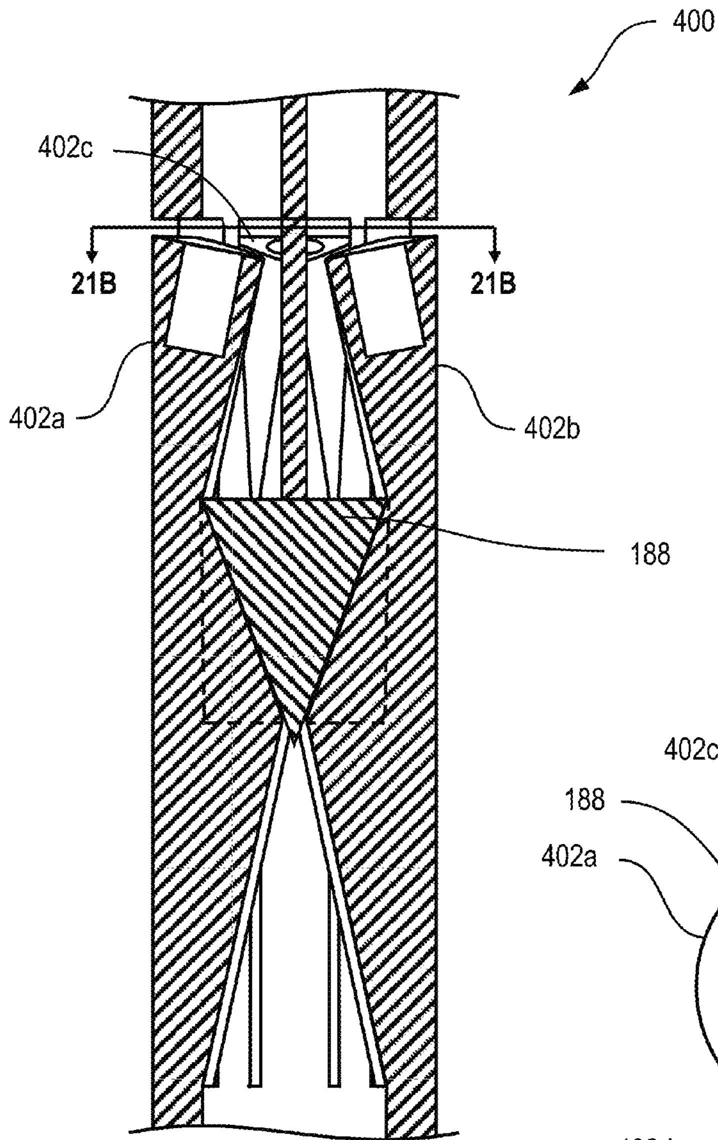


Fig. 20



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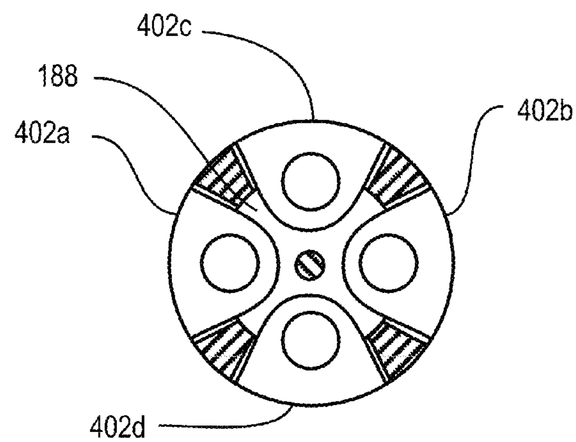

Fig. 21B

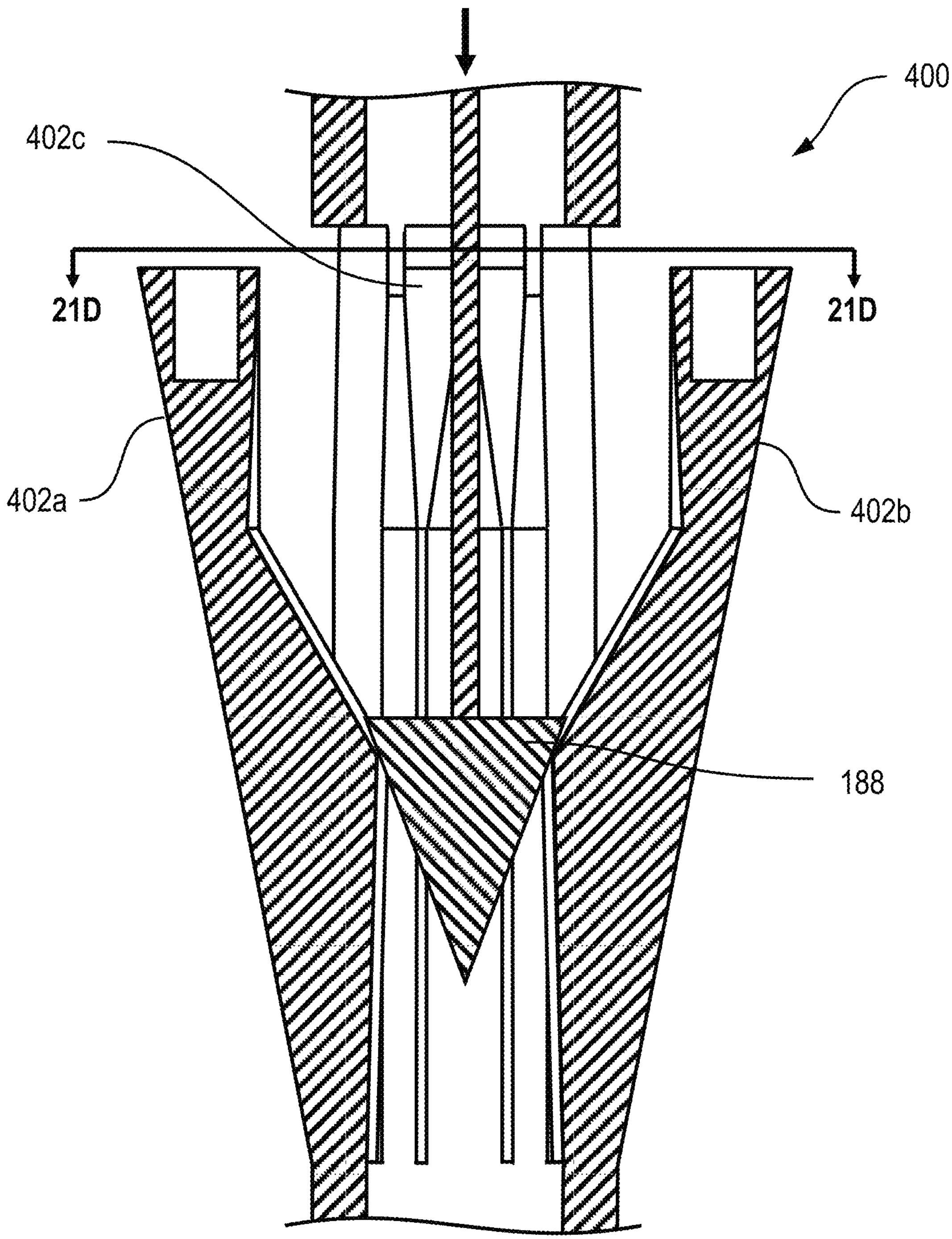

Fig. 21C

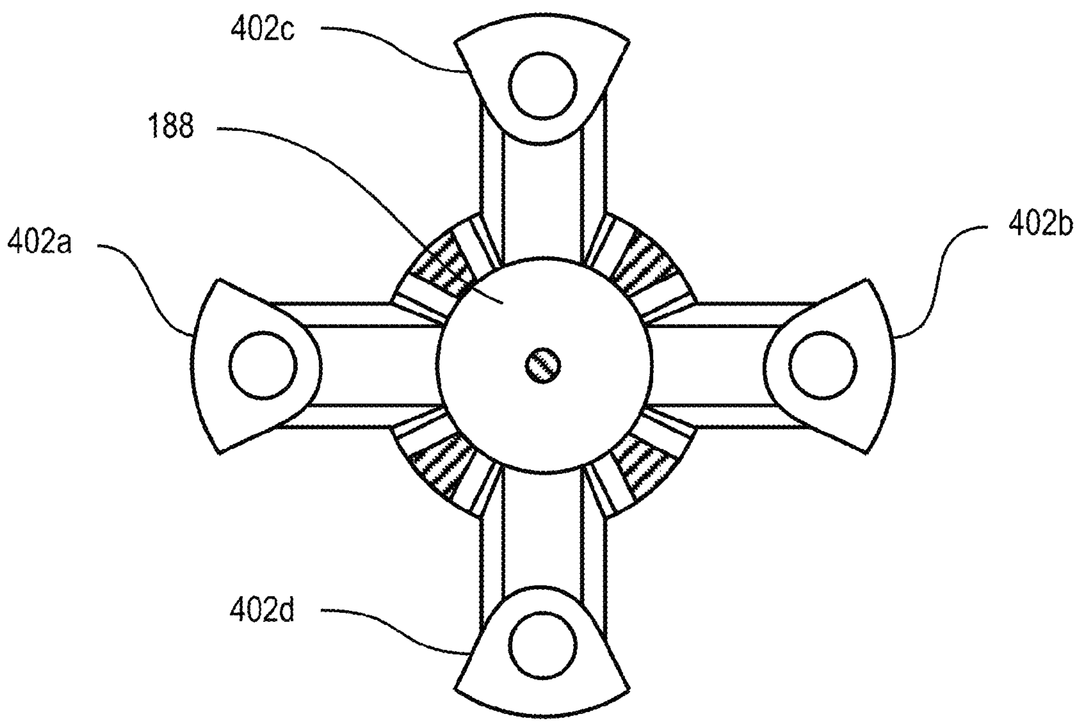

Fig. 21D

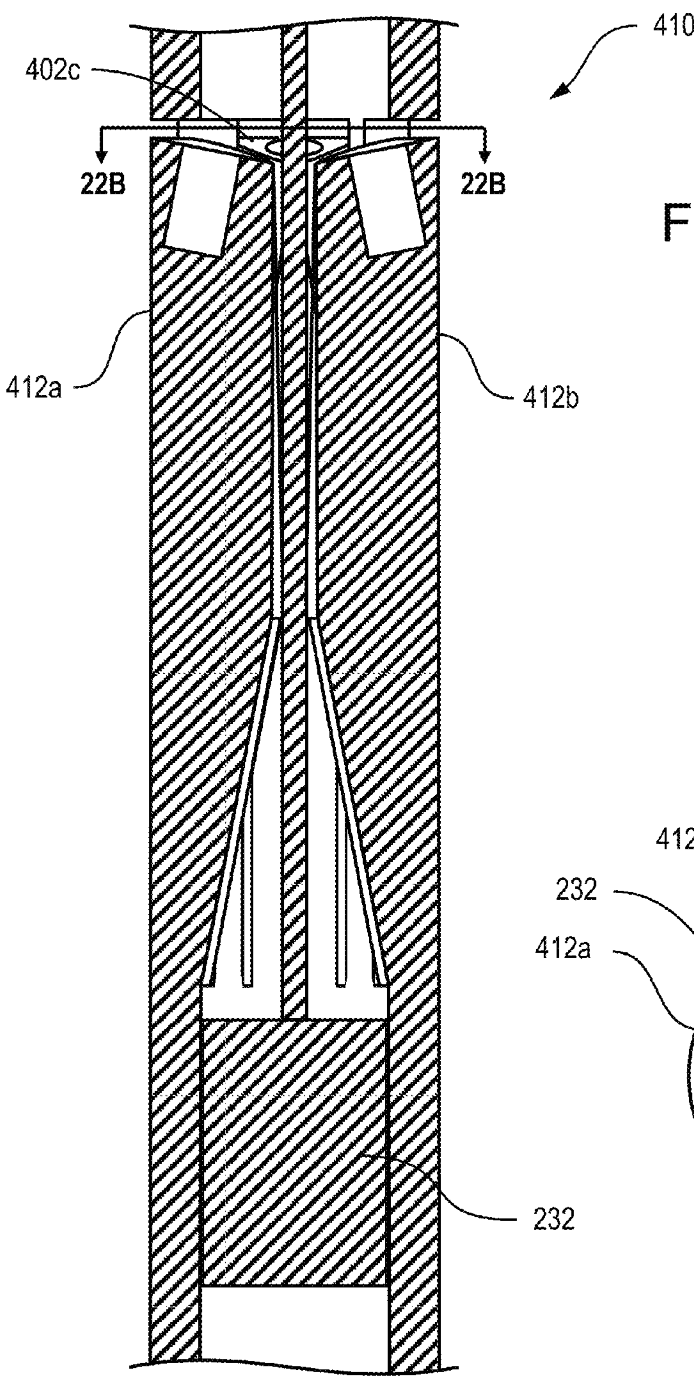

Fig. 22A

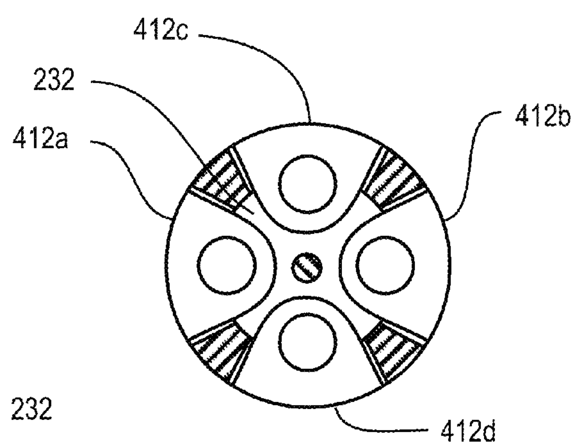

Fig. 22B

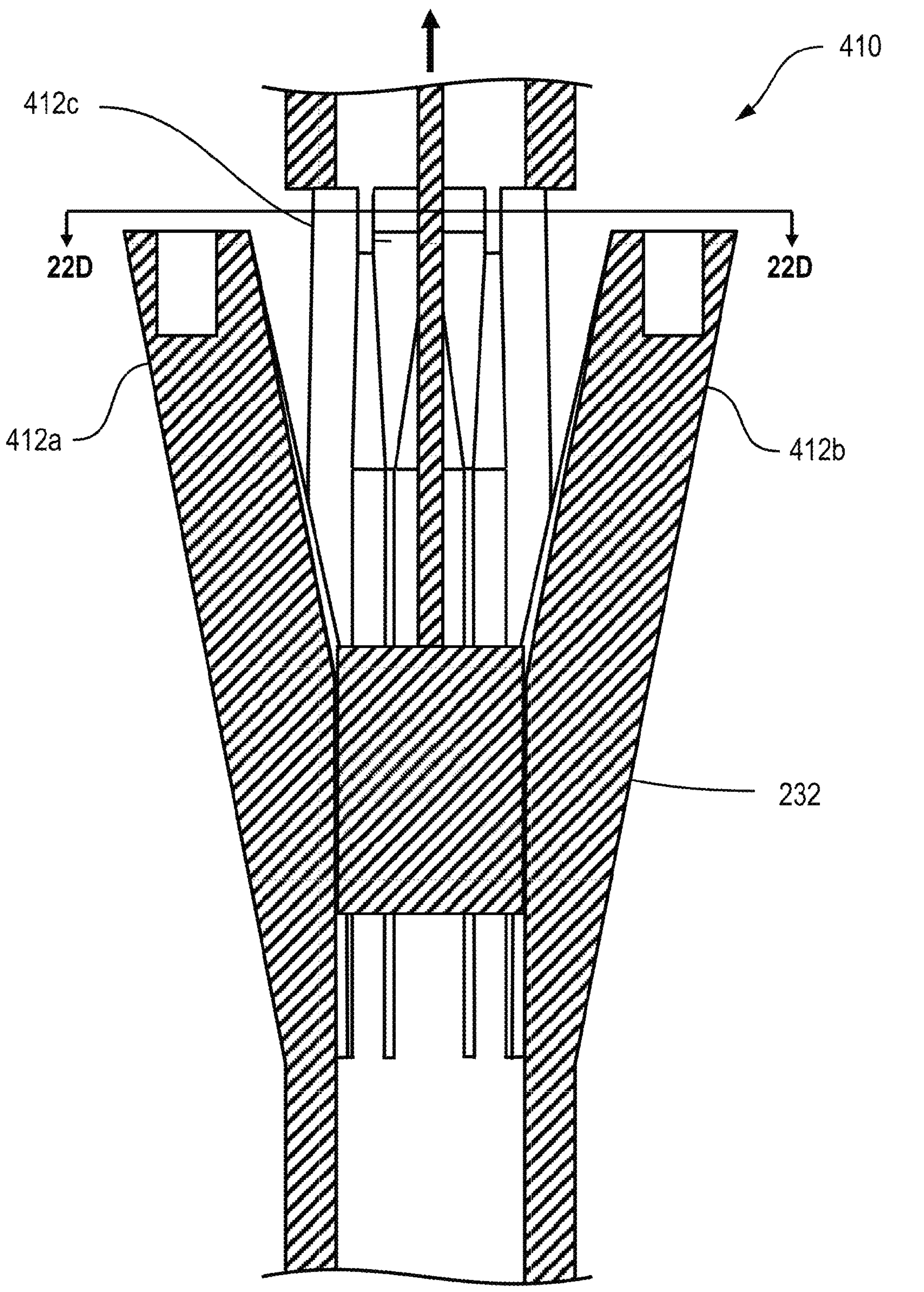

Fig. 22C

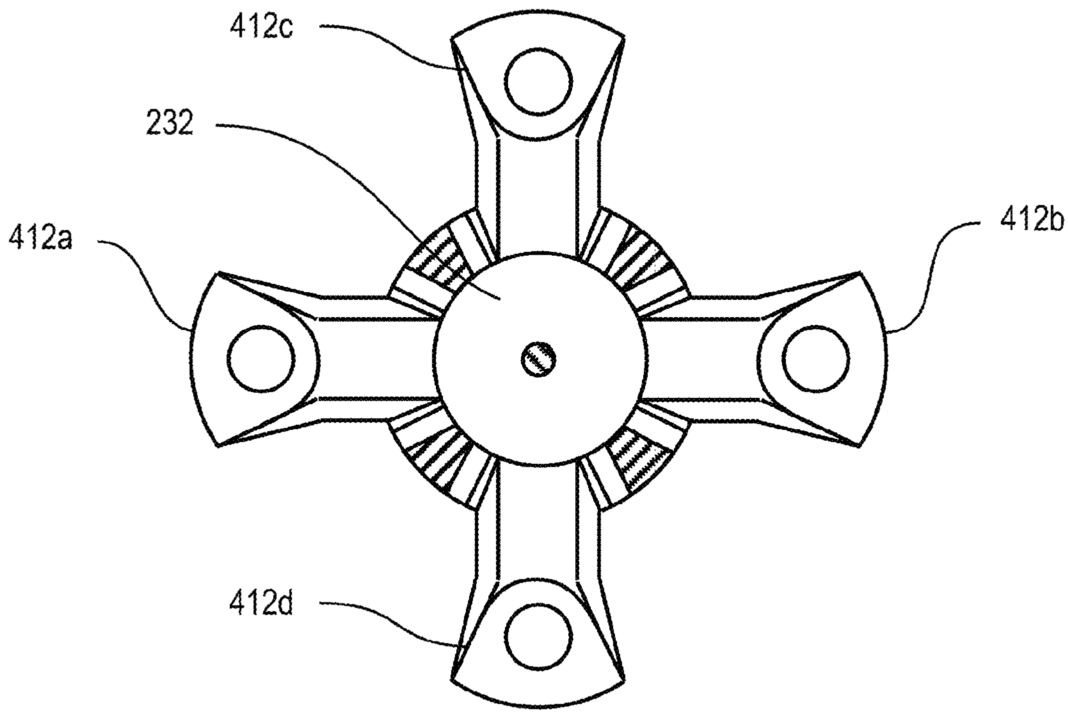

Fig. 22D

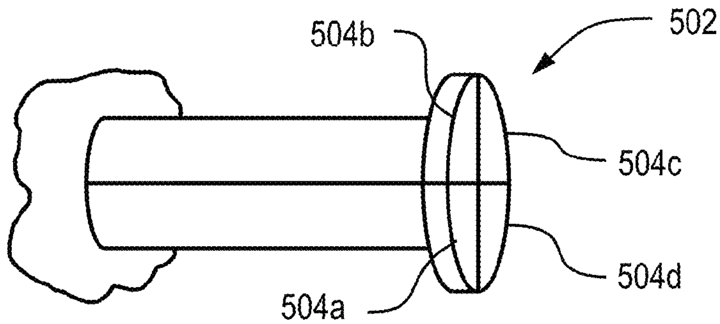

Fig. 23A

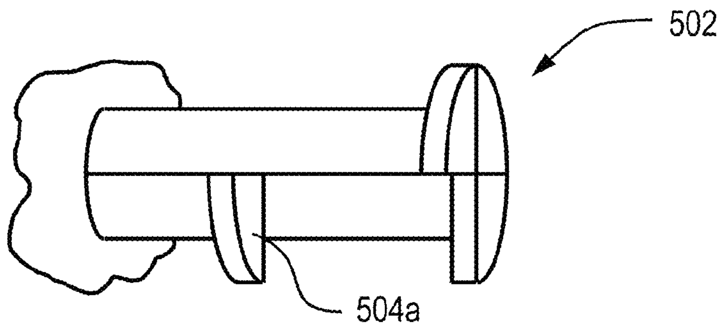

Fig. 23B

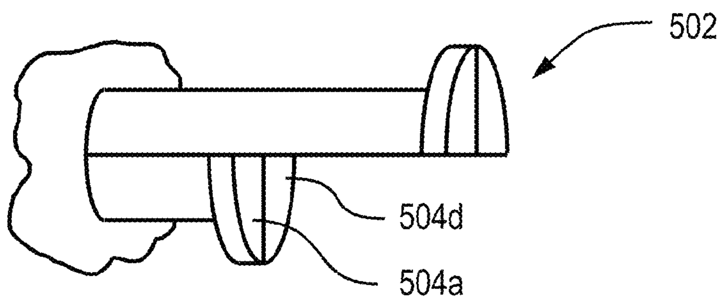

Fig. 23C

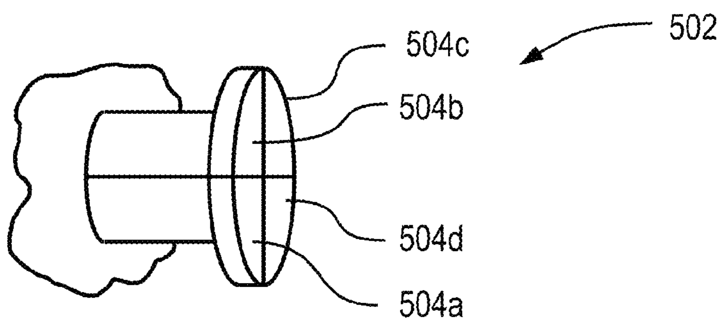

Fig. 23D

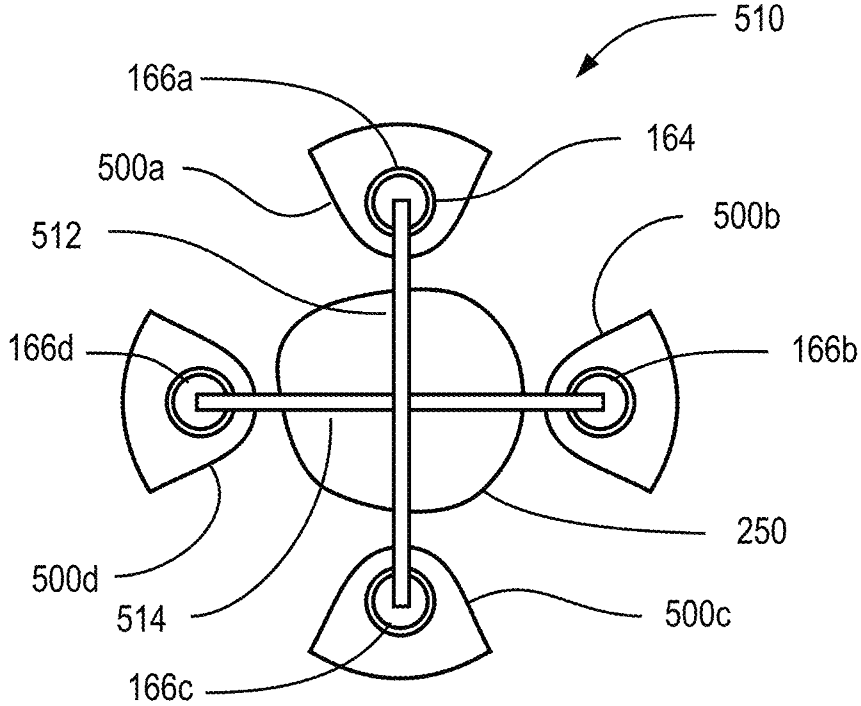

Fig. 24A

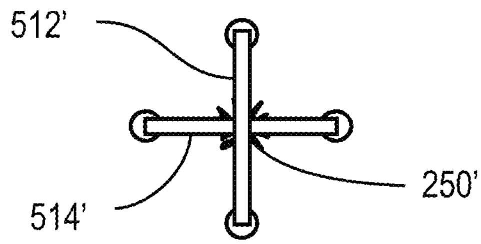

Fig. 24B

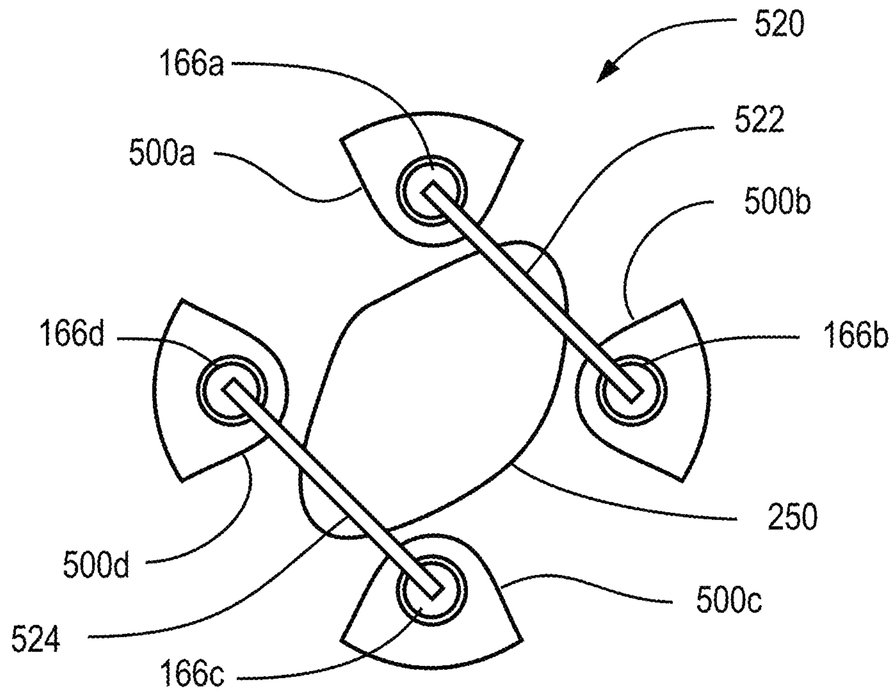

Fig. 25A

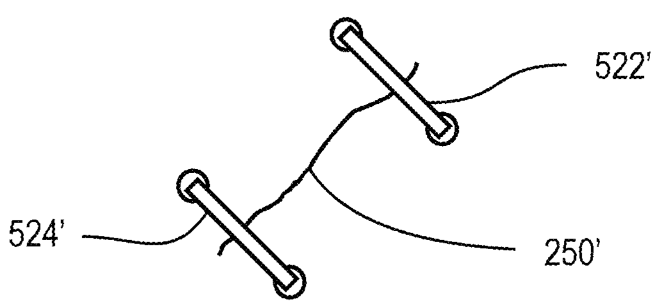

Fig. 25B

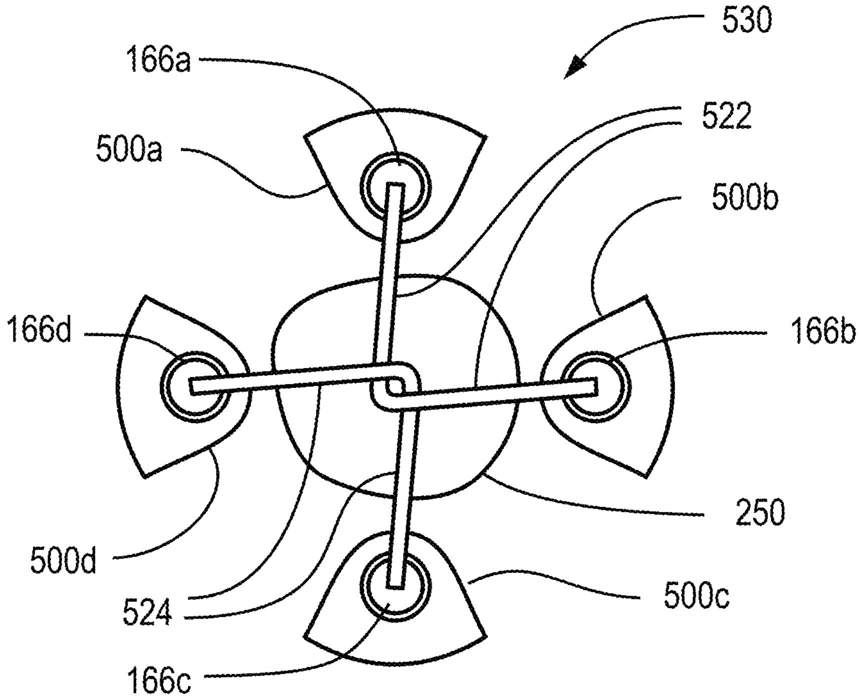

Fig. 26A

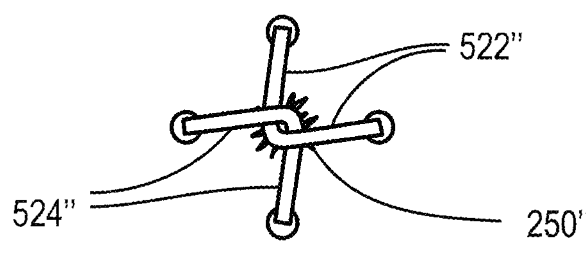

Fig. 26B

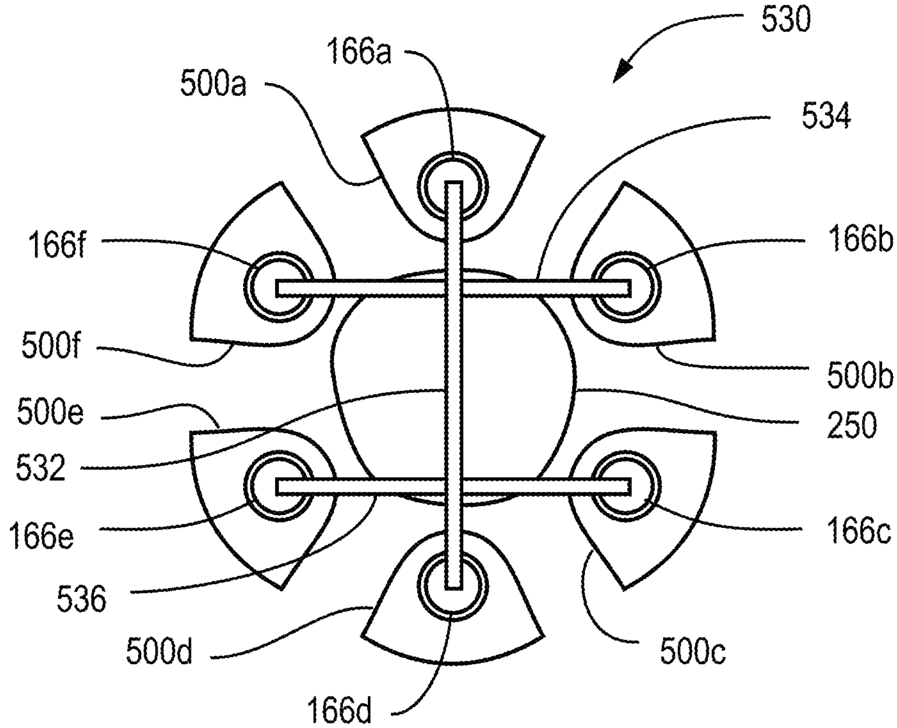

Fig. 27A

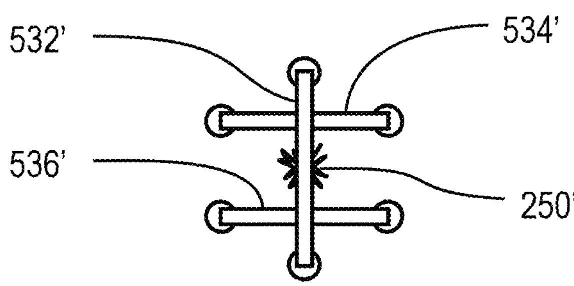

Fig. 27B

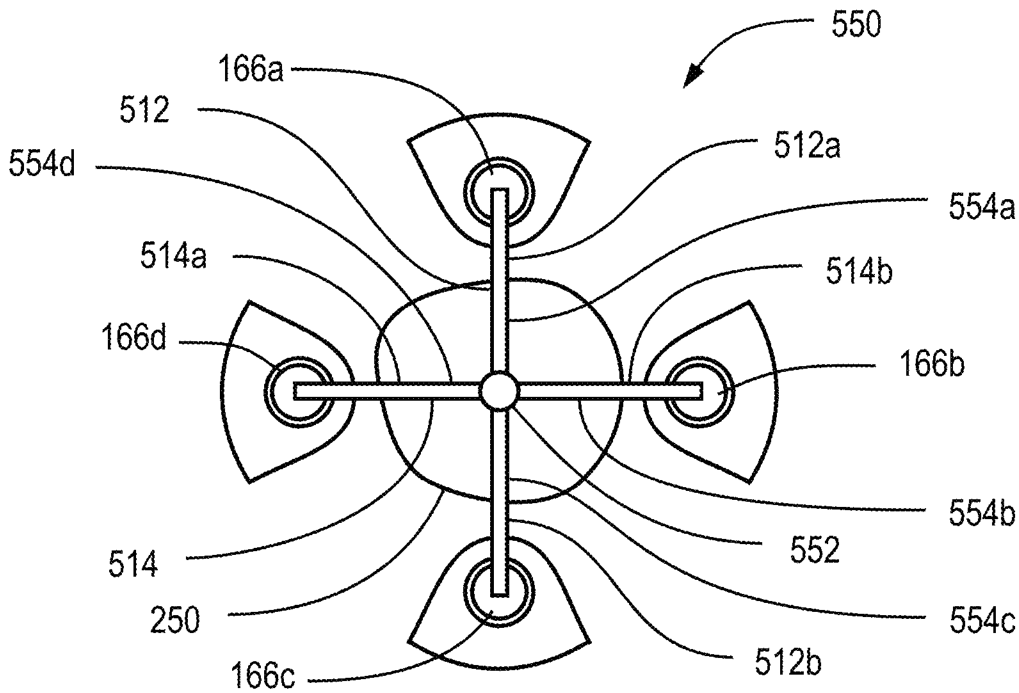

Fig. 28A

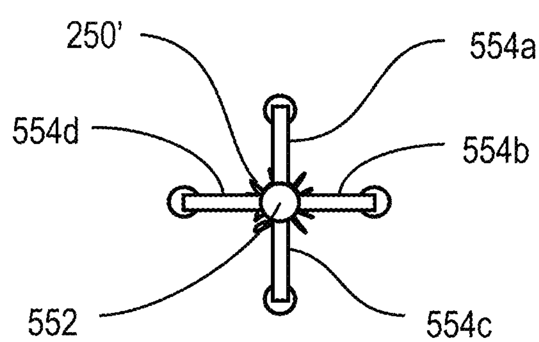

Fig. 28B

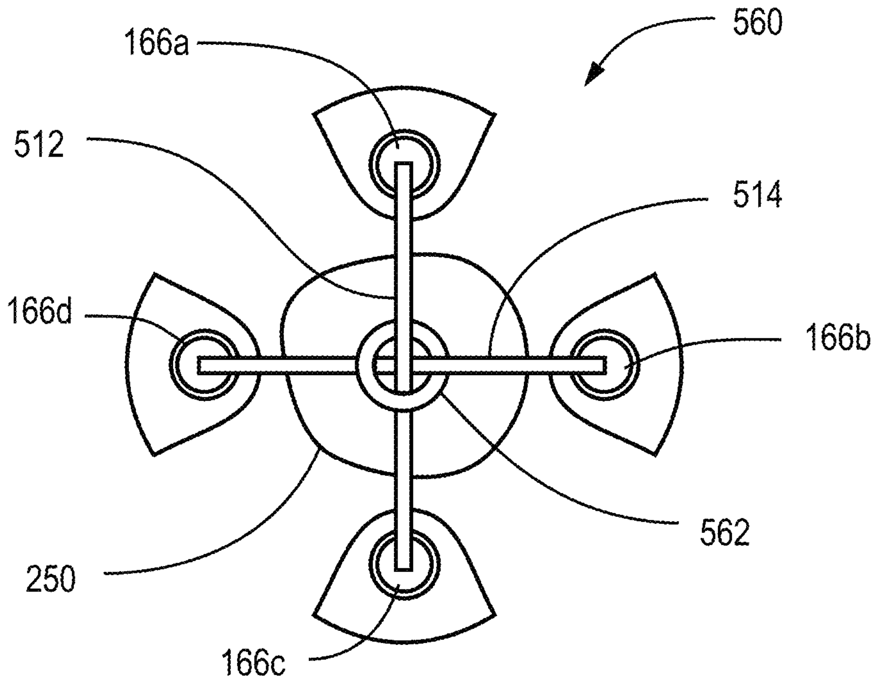

Fig. 29A

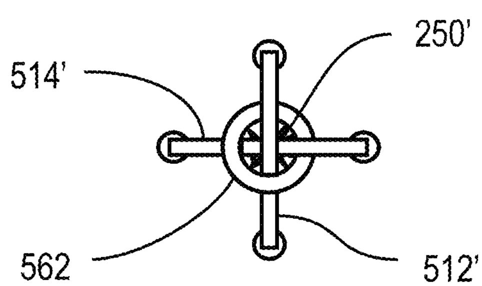

Fig. 29B

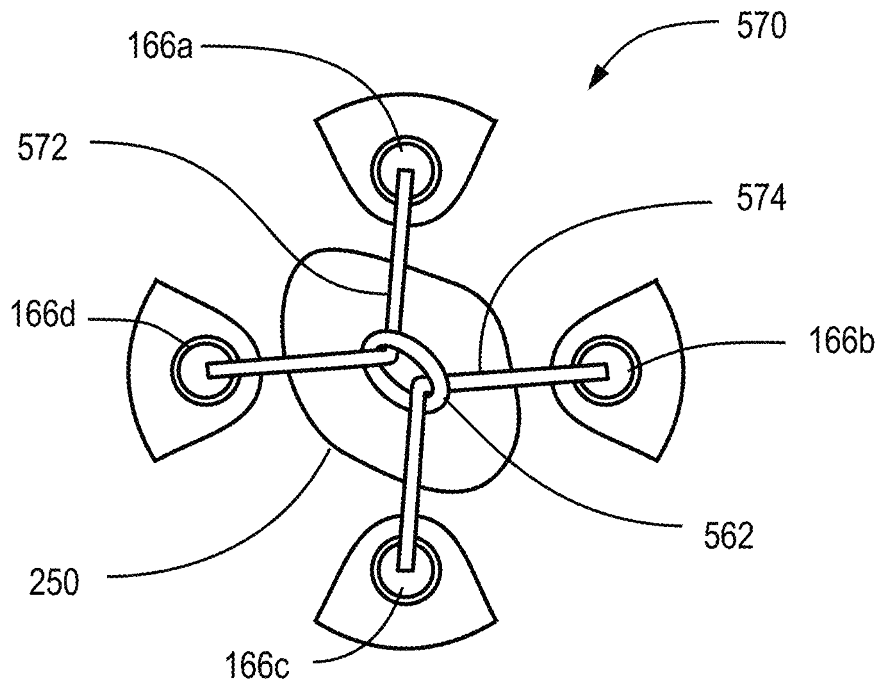

Fig. 30A

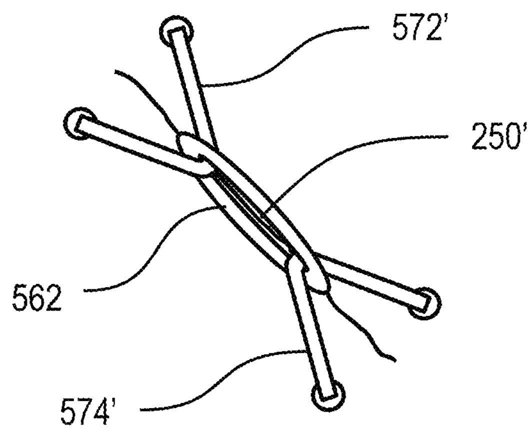

Fig. 30B

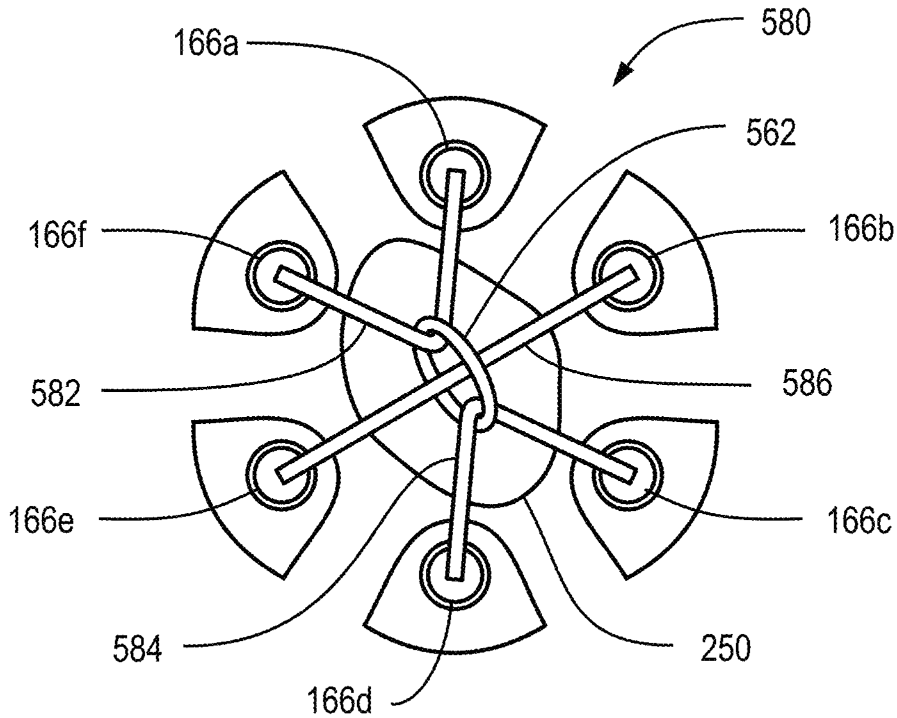

Fig. 31A

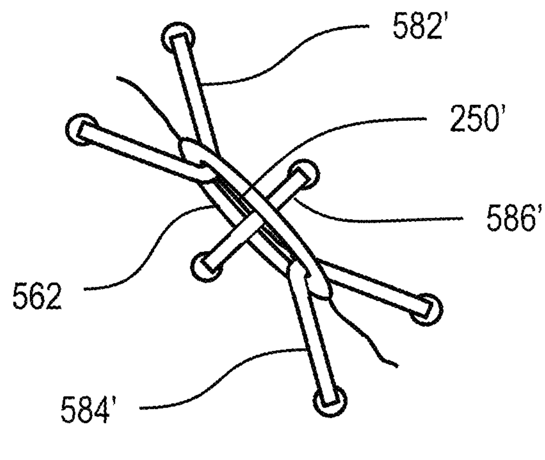

Fig. 31B

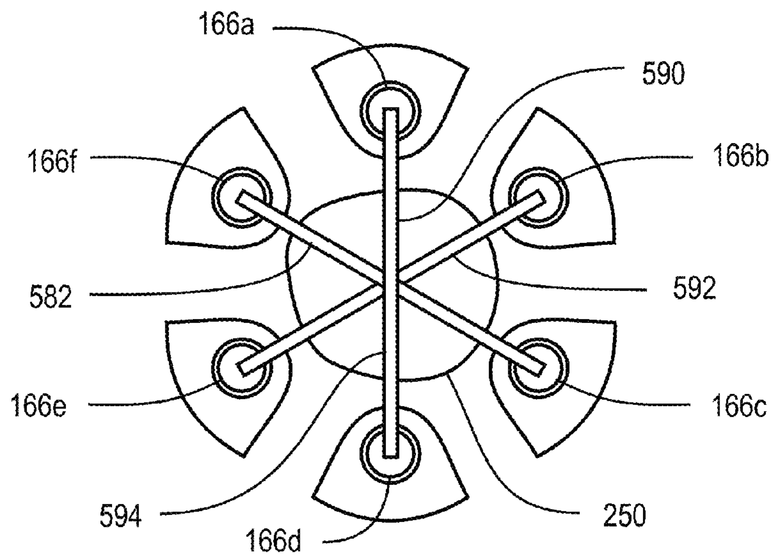

Fig. 32A

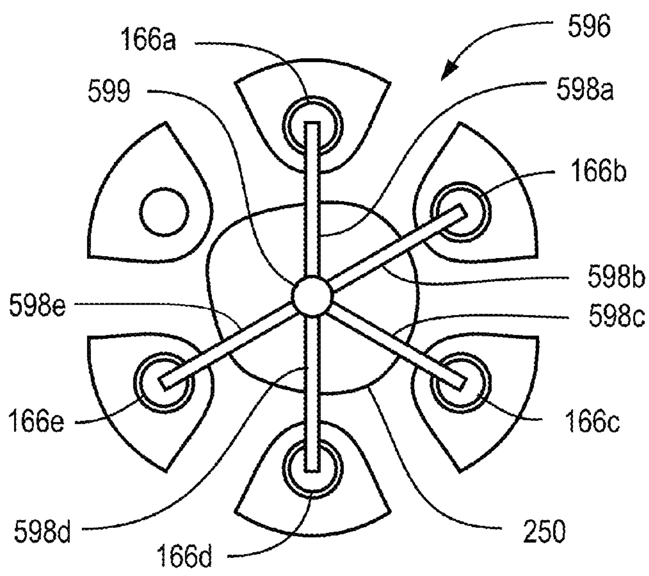

Fig. 32B

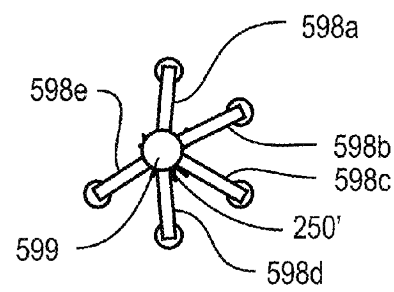

Fig. 32C

ARTICULATING SUTURING DEVICE

BACKGROUND OF THE INVENTION

1. The Field of the Invention

The present disclosure provides apparatuses and methods that are suitable for closure of vascular punctures or other openings in bodily tissues. More particularly, the present disclosure relates to apparatuses and techniques for tightening sutures about an opening to close the opening, which is usually accessed through a tissue tract.

2. The Relevant Technology

A number of diagnostic and interventional vascular procedures are now performed translumenally. A catheter is introduced to the vascular system at a convenient access location and guided through the vascular system to a target location using established techniques. Such procedures require vascular access, which is usually established during the well-known Seldinger technique, as described, for example, in William Grossman's "Cardiac Catheterization and Angioplasty," 3.sup.rd Ed., Lea and Febiger, Philadelphia, 1986, incorporated herein by reference. Vascular access is generally provided through an introducer sheath, which is positioned to extend from outside the patient body into the vascular lumen.

When vascular access is no longer required, the introducer sheath is removed and bleeding at the puncture site stopped. One common approach for providing hemostasis (the cessation of bleeding) is to apply external force near and upstream from the puncture site, typically by manual or "digital" compression. This approach suffers from a number of disadvantages. It is time consuming, frequently requiring a half hour or more of compression before hemostasis is assured. Additionally, such compression techniques rely on clot formation, which can be delayed until anticoagulants used in vascular therapy procedures (such as for heart attacks, stent deployment, non-optical PTCA results, and the like) wear off. This can take up to two to four hours, thereby increasing the time required before completion of the compression technique. The compression procedure is further uncomfortable for the patient and frequently requires analgesics to be tolerable. Moreover, the application of excessive pressure can at times totally occlude the underlying blood vessel, resulting in ischemia and/or thrombosis. Following manual compression, the patient typically remains recumbent from four to as much as twelve hours or more under close observation so as to assure continued hemostasis. During this time renewed bleeding may occur, resulting in blood loss through the tract, hematoma and/or pseudoaneurysm formation, as well as arteriovenous fistula formation. These complications may require blood transfusion and/or surgical intervention.

The incidence of complications from compression-induced hemostasis increases when the size of the introducer sheath grows larger, and/or when the patient is anticoagulated. It is clear that the compression technique for arterial closure can be risky, and is expensive and onerous to the patient. Although the risk of complications can be reduced by using highly trained individuals, dedicating such personnel to this task is both expensive and inefficient. Nonetheless, as the number and efficacy of translumenally performed diagnostic and interventional vascular procedures increases, the number of patients requiring effective hemostasis for a vascular puncture continues to increase.

To overcome the problems associated with manual compression, the use of bioabsorbable fasteners or sealing bodies to stop bleeding has previously been proposed. Generally, these approaches rely on the placement of a thrombogenic and bioabsorbable material, such as collagen, at the superficial arterial wall over the puncture site. While potentially effective, this approach suffers from a number of problems. It can be difficult to properly locate the interface of the overlying tissue and the adventitial surface of the blood vessel. Locating the fastener too far from that interface can result in failure to provide hemostasis, and subsequent hematoma and/or pseudo-aneurysm formation. Conversely, if the sealing body intrudes into the arterial lumen, intravascular clots and/or collagen pieces with thrombus attached can form and embolize downstream, causing vascular occlusion. Also, thrombus formation on the surface of a sealing body protruding into the lumen can cause a stenosis, which can obstruct normal blood flow. Other possible complications include infection, as well as adverse reaction to the collagen or other implant.

A more effective approach for vascular closure has been proposed in U.S. Pat. Nos. 5,417,699, 5,613,974; and PCT published Patent Application No. PCT/US96/10271 filed on Jun. 104, 1996, the full disclosures of which are incorporated herein by reference. A suture-applying device is introduced through the tissue tract with a distal end of the device extending through the vascular puncture. One or more needles in the device are then used to draw suture through the blood vessel wall on opposite sides of the puncture, and the suture is secured directly over the adventitial surface of the blood vessel wall to provide highly reliable closure.

While a significant improvement over the use of manual pressure, clamps, and collagen plugs, certain design criteria have been found to be important to successful suturing to achieve vascular closure. For example, it is highly beneficial to properly direct the needles through the blood vessel wall at a significant distance from the puncture so that the suture is well anchored in the tissue and can provide tight closure. It is also highly beneficial to insure that the needle deployment takes place when the device is properly positioned relative to the vessel wall. The ease of deployment and efficacy of the procedure can further be enhanced by reducing the cross-section of that portion of the device, which is inserted into the tissue tract and/or the vessel itself, which may also allow closure of the vessel in a relatively short amount of time without imposing excessive injury to the tissue tract or vessel.

For the above reasons, it would be desirable to provide improved devices, systems, and methods for suturing vascular punctures. The new device should have the capability of delivering one or more pre-tied knot to an incision site. It would be particularly beneficial if these improved devices provided some or all of the benefits while overcoming one or more of the disadvantages discussed above.

BRIEF SUMMARY OF THE INVENTION

The present disclosure provides apparatuses and methods that are suitable for closure of vascular punctures or other openings in bodily tissues. More particularly, the present disclosure relates to apparatuses and techniques for tightening sutures about a tissue opening to close the opening, which is usually accessed through a tissue tract.

In one aspect of the invention, there is provided an apparatus for closing an opening in a body tissue. The apparatus has a shaft, first and second arms, and an expander. The shaft extends along an axis between a proximal end and a spaced apart distal end. The shaft has a size and configuration suitable for insertion through an opening in body tissue. The first and second arms each extend between a proximal end and a distal end. The distal end of each arm is hingedly attached to or integrally formed with the shaft. The first and second arms are movable between a retracted configuration, in which the first and second arms are each aligned along the shaft, and a deployed configuration, in which the proximal end of each of the first and second arms pivot respectively about the distal end of the respective arm so as to extend laterally away from the shaft. The expander is positioned within the shaft, and movement of the expander causes the first and second arms to move between the retracted and deployed configurations.

The proximal ends of the arms can extend laterally away from the shaft in opposite directions in the deployed configuration. The expander can be positioned within a lumen of the shaft, can be substantially conical, and can be threaded. Movement of the expander in the distal direction can cause the proximal ends of the arms to laterally move to the deployed configuration. Alternatively, movement of the expander in the proximal direction can cause the proximal ends of the arms to laterally move to the deployed configuration.

The apparatus can also include a flexible filament having first and second ends that are removably coupled with the first and second arms, respectively, and first and second penetrators positioned proximal of the first and second arms. The first and second penetrators can be advanceable distally from the shaft to the first and second arms in the deployed configuration.

The apparatus can also include third and fourth arms, each extending between a proximal end and a distal end. The distal ends of the third and fourth arms can be hingedly attached to or integrally formed with the shaft and the fourth arm can be laterally spaced apart from the third arm. The third and fourth arms can also be movable between a retracted configuration, in which the third and fourth arms are each aligned along the shaft, and a deployed configuration, in which the proximal end of each of the third and fourth arms pivot respectively about the distal end of the respective arm so as to extend laterally away from the shaft. The third and fourth arms can be caused to move between the retracted and deployed configurations by movement of the expander. The proximal ends of the third and fourth arms can extend laterally away from the shaft in opposite directions in the deployed configuration that are different than the lateral directions of the proximal ends of the first and second arms.

The apparatus can also include a second flexible filament having first and second ends that are removably coupled with the third and fourth arms, respectively, and third and fourth penetrators positioned proximal of the third and fourth arms. The third and fourth penetrators can be advanceable distally from the shaft to the third and fourth arms in the deployed configuration.

In another aspect of the invention there is provided a method for closing an opening extending through a tissue wall. The method includes the steps of inserting a distal end of a tissue locator distally through the opening, the tissue locator comprising a first arm and a second arm each extending between a proximal end and a distal end, the first and second arms each being aligned along a shaft of the tissue locator in a retracted configuration, the tissue locator being inserted far enough through the opening that the first and second arms are positioned distal of the tissue wall, first and second ends of a flexible filament respectively being removably coupled with the first and second arms; pivoting the proximal end of each of the first and second arms of the tissue locator about the distal end of the respective arm to move the proximal ends of the first and second arms from the retracted configuration to a deployed configuration in which the proximal ends of the first and second arms extend laterally away from the shaft; advancing a first penetrator and a second penetrator distally through the vessel wall such that the first and second penetrators respectively couple with the first and second ends of the flexible filament; and withdrawing the first and second penetrators proximally through the vessel wall, thereby causing the first and second ends of the filament to uncouple from the first and second arms, the first end of the flexible filament remaining coupled with the first penetrator such that the first end of the filament withdraws proximally through the vessel wall with the first penetrator.

The distal ends of the arms can remain aligned along a shaft of the tissue locator in the deployed configuration. The distal ends of the arms can be integrally formed with the shaft of the tissue locator. Alternatively, the distal ends of the arms can be hingedly attached to the shaft of the tissue locator. The distal ends of the arms can flex outward when the proximal ends of the arms move to the deployed configuration. The proximal ends of the first and second arms can extend in opposite lateral directions when the arms are in the deployed configuration. The second end of the flexible filament can remain coupled with the second penetrator such that the second end of the filament withdraws proximally through the vessel wall with the second penetrator.

The step of pivoting the proximal ends of the arms can be accomplished by moving an arm expander axially along the shaft so as to cause a laterally outward force to occur on the arms. The step of moving the arm expander axially can be accomplished by moving the arm expander proximally to cause the laterally outward force to occur on the arms. Alternatively, the step of moving the arm expander axially can be accomplished by moving the arm expander distally to cause the laterally outward force to occur on the arms.

The tissue locator can further include third and fourth arms each extending between a proximal end and a distal end, and first and second ends of a second flexible filament can be removably coupled with the third and fourth arms. The third and fourth arms can also each be aligned along the shaft of the tissue locator in the retracted configuration and positioned distal of the tissue wall when the tissue locator is inserted through the opening.

The method can further include: pivoting the proximal end of each of the third and fourth arms of the tissue locator about the distal end of the respective arm to move the proximal ends of the third and fourth arms from the retracted configuration to a deployed configuration in which the proximal ends of the third and fourth arms extend laterally away from the shaft; advancing a third penetrator and a fourth penetrator distally through the vessel wall such that the third and fourth penetrators respectively couple with the first and second ends of the second flexible filament; and withdrawing the third and fourth penetrators proximally through the vessel wall, thereby causing the first and second ends of the second filament to uncouple from the third and fourth arms, the first end of the second flexible filament remaining coupled with the third penetrator such that the first end of the second filament withdraws proximally through the vessel wall with the third penetrator.

The second end of the second flexible filament can remain coupled with the fourth penetrator such that the second end of the second filament withdraws proximally through the vessel wall with the fourth penetrator.

The step of pivoting the proximal end of each of the third and fourth arms of the tissue locator can be performed concurrently with pivoting the proximal end of each of the first and second arms; and the step of withdrawing the third and fourth penetrators proximally through the vessel wall can be performed concurrently with drawing the first and second penetrators proximally through the vessel wall. The proximal ends of the third and fourth arms can extend in opposite lateral directions from each other and in lateral directions different than the lateral directions of the proximal ends of the first and second arms when the third and fourth arms are in the deployed configuration. The step of moving the arm expander axially along the shaft can also cause a laterally outward force to occur on the third and fourth arms to pivot the third and fourth arms laterally outward.

In another aspect of the invention, there is provided an apparatus for closing an opening in a body tissue. The apparatus has a shaft, three or more arms, and an expander. The shaft extends along an axis and has a size and configuration suitable for insertion through an opening in body tissue. The three arms are attached to or integrally formed with the shaft and are laterally spaced apart from each other. The arms are movable between a retracted configuration, in which the arms are each aligned along the shaft, and a deployed configuration, in which the arms each extend laterally away from the shaft in different directions. The expander causes the arms to move between the retracted and deployed configurations.

The apparatus can include a plurality of flexible filaments each having first and second ends that are removably coupled with separate ones of the three or more arms, and a penetrator associated with each arm. Each penetrator can be positioned proximal of the respective arm, and can be advanceable distally from the shaft to the respective arm in the deployed configuration.

The apparatus can include a suture net having multiple ends that are each removably coupled with separate ones of the three or more arms, and a penetrator associated with each arm. Each penetrator can be positioned proximal of the respective arm, and can be advanceable distally from the shaft to the respective arm in the deployed configuration.

The three or more arms can be four to six arms. The expander can be positioned within a lumen of the shaft.

In another aspect of the invention there is provided a method for closing an opening extending through a tissue wall. The method includes the steps of inserting a distal end of a tissue locator distally through the opening, the tissue locator comprising three or more arms, each being aligned along a shaft of the tissue locator in a retracted configuration, the tissue locator being inserted far enough through the opening that the three or more arms are positioned distal of the tissue wall, an end of a filament or a filament net link being removably coupled with each of the arms; pivoting the proximal ends of each of the first and second moving the three or more arms of the tissue locator from the retracted configuration to a deployed configuration in which the three or more arms extend laterally away from the shaft in different directions; for each arm, advancing a penetrator distally through the vessel wall to couple with the end of the filament net or flexible filament associated with the arm; and withdrawing the penetrators proximally through the vessel wall, thereby causing the ends of the filament net or the filaments to uncouple from the three or more arms, at least one end of the filament net or of each flexible filament remaining coupled with at least one of the penetrators such that the corresponding end of the filament net or each filament withdraws proximally through the vessel wall with the corresponding penetrator.

All of the ends of the filament net or flexible filaments can remain coupled with the corresponding penetrators such that all of the ends of the filament net or flexible filaments withdraw proximally through the vessel wall with the three or more penetrators.

In another aspect of the invention, there is provided an apparatus for closing an opening in a body tissue. The apparatus has a shaft, a plurality of arms, a plurality of flexible filaments, and a penetrator associated with each arm. The shaft extends along an axis between a proximal end and a spaced apart distal end and has a size and configuration suitable for insertion through an opening in body tissue. The plurality of arms are attached to or integrally formed with the shaft. The plurality of flexible filaments each has a first end and a second end; the first and second ends of the flexible filaments are removably coupled with separate ones of the plurality of arms. Each penetrator is positioned proximal of the respective arm and is advanceable distally through a vessel wall to the respective arm to couple with the end of the filament associated with the arm. The penetrators are configured to withdraw at least a portion of each of the filaments through the vessel wall.

The arms can be laterally spaced apart from each other. The arms can be movable between a retracted configuration, in which the arms are each aligned along the shaft; and a deployed configuration in which the arms extend laterally away from the shaft. The apparatus can also include an expander which causes the arms to move between the retracted and deployed configurations. The expander can be positioned within a lumen of the shaft.

In another aspect of the invention there is provided a method for closing an opening extending through a tissue wall. The method includes the steps of inserting a distal end of a tissue locator distally through the opening, the tissue locator comprising a plurality of arms, each being aligned along a shaft of the tissue locator in a retracted configuration, the tissue locator being inserted far enough through the opening that the plurality of arms are positioned distal of the tissue wall, a plurality of flexible filaments being removably coupled with the plurality of arms; moving the plurality of arms from the retracted configuration to a deployed configuration in which the plurality of arms extend laterally away from the shaft; for each arm, advancing a penetrator distally through the vessel wall to couple with an end of one of the flexible filaments; and withdrawing the penetrators proximally through the vessel wall, thereby causing the ends of the filaments to uncouple from the plurality of arms, at least one end of each of the flexible filaments remaining coupled with the respective penetrator such that the coupled ends of the filaments withdraw proximally through the vessel wall with the respective penetrators.

All of the ends of the flexible filaments can remain coupled with the corresponding penetrators such that all of the ends of the filaments withdraw proximally through the vessel wall with the penetrators.

In another aspect of the invention, there is provided an apparatus for closing an opening in a body tissue. The apparatus has a shaft, a plurality of arms, a flexible net, and a penetrator associated with each arm. The shaft extends along an axis between a proximal end and a spaced apart distal end and has a size and configuration suitable for insertion through an opening in body tissue. The plurality of arms are attached to or integrally formed with the shaft. The filament net has plurality of ends; each end of the filament net is removably coupled with a separate one of the arms. Each penetrator is positioned proximal of the respective arm and is advanceable distally through a vessel wall to the respective arm to couple with the end of the filament net associated with the arm. The penetrators are configured to withdraw the ends of the filament net through the vessel wall.

The arms can be laterally spaced apart from each other. The arms can be movable between a retracted configuration, in which the arms are each aligned along the shaft; and a deployed configuration in which the arms extend laterally away from the shaft. The apparatus can also include an expander which causes the arms to move between the retracted and deployed configurations. The expander can be positioned within a lumen of the shaft. The apparatus can also include a flexible filament removably coupled with separate ones of the arms.

In another aspect of the invention there is provided a method for closing an opening extending through a tissue wall. The method includes the steps of inserting a distal end of a tissue locator distally through the opening, the tissue locator comprising a plurality of arms, each being aligned along a shaft of the tissue locator in a retracted configuration, the tissue locator being inserted far enough through the opening that the plurality of arms are positioned distal of the tissue wall, separate ends of a filament net being removably coupled with each of the arms; moving the plurality of arms of the tissue locator from the retracted configuration to a deployed configuration in which the plurality of arms extend laterally away from the shaft; for each arm, advancing a penetrator distally through the vessel wall to couple with the end of the filament net associated with the arm; and withdrawing the penetrators proximally through the vessel wall, thereby causing the ends of the filament net to uncouple from the plurality of arms and withdraw proximally through the vessel wall with the penetrators.

The step of moving the plurality of arms of the tissue locator can be accomplished by pivoting a proximal end of each arm about a distal end of the respective arm.

In another aspect of the invention, there is provided an apparatus for closing an opening in a body tissue. The apparatus has a shaft, a plurality of arms, a filament net or plurality of flexible filaments, a penetrator associated with each arm, and a plurality of penetrator actuators. The shaft extends along an axis between a proximal end and a spaced apart distal end and has a size and configuration suitable for insertion through an opening in body tissue. The plurality of arms are attached to or integrally formed with the shaft and are movable between a retracted configuration, in which the arms are each aligned along the shaft of the tissue locator, and a deployed configuration in which the arms extend laterally away from the shaft. The filament net or plurality of flexible filaments have multiple ends and each of the ends are removably coupled with a separate one of the plurality of arms. Each penetrator is positioned proximal of the respective arm and is advanceable distally through a vessel wall to the respective arm to couple with the end of the filament or filament net associated with the arm. The penetrators are configured to withdraw the ends of the filament or filament net through the vessel wall. The actuators are each associated with a different penetrator so that the penetrators are movable independent of each other by the penetrator actuators.

In another aspect of the invention there is provided a method for closing an opening extending through a tissue wall. The method includes the steps of inserting a distal end of a tissue locator distally through the opening, the tissue locator comprising a plurality of arms, each being aligned along a shaft of the tissue locator in a retracted configuration, the tissue locator being inserted far enough through the opening that the plurality of arms are positioned distal of the tissue wall, at least one flexible filament or web being removably coupled with the plurality of arms; moving the plurality of arms from the retracted configuration to a deployed configuration in which the plurality of arms extend laterally away from the shaft; for each arm, advancing a penetrator distally through the vessel wall to couple with the at least one flexible filament or web associated with the arm, the penetrators being movable independent of each other; and withdrawing the penetrators proximally through the vessel wall, thereby causing the at least one flexible filament or web to uncouple from the plurality of arms and withdraw proximally through the vessel wall with the penetrators.

Each penetrator can be advanced at different times from each other. Each penetrator can have a separate penetrator actuator associated therewith and can be advanced and withdrawn by manually manipulating the associated penetrator actuator.

In another aspect of the invention there is provided a method for closing an opening extending through a tissue wall. The method includes the steps of inserting a distal end of a tissue locator distally through the opening, the tissue locator comprising a plurality of arms, each being aligned along a shaft of the tissue locator in a retracted configuration, the tissue locator being inserted far enough through the opening that the plurality of arms are positioned distal of the tissue wall; advancing a plurality of penetrators distally to attempt to penetrate through the vessel wall, each penetrator being associated with a different one of the arms, one or more penetrators not penetrating through the vessel wall; removably coupling separate ends of a filament net with the plurality of arms, the one or more arms associated with the nonpenetrating penetrators not being coupled with the filament net; moving the plurality of arms from the retracted configuration to a deployed configuration in which the plurality of arms extend laterally away from the shaft; for each arm associated with penetrating penetrators, advancing a penetrator distally to penetrate through the vessel wall, the penetrators penetrating through the wall to couple with the end of the filament net associated with the corresponding arm; and withdrawing the penetrators proximally, thereby causing the ends of the filament net to uncouple from the plurality of arms and withdraw proximally through the vessel wall with the penetrators.

These and other advantages and features of the present disclosure will become more fully apparent from the following description and appended claims, or may be learned by the practice of the disclosure as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the present invention will now be discussed with reference to the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. In the drawings, like numerals designate like elements. Furthermore, multiple instances of an element may each include separate letters appended to the element number. For example two instances of a particular element "**20**" may be labeled as "**20***a*" and "**20***b*". In that case, the element label may be used without an appended letter (e.g., "**20**") to generally refer to every instance of the element; while the element label will include an appended letter (e.g., "**20***a*") to refer to a specific instance of the element.

FIGS. **1**A and **1**B are perspective views of a tissue closure device, respectively showing a pair of arms in retracted and deployed positions according to one embodiment of the present invention;

FIGS. **2**A-C are perspective views of a tissue closure device according to another embodiment, showing actuation of a pair of arms and advancement of needles from a shaft to the arms;

FIGS. **3**A-**3**D are cross-sectional side and top views of one embodiment of a tissue locator that can be used in the tissue closure devices shown in FIGS. **1** and **2** showing the arms in the retracted position (FIGS. **3**A and **3**B) and in the deployed position (FIGS. **3**C and **3**D). FIG. **3**B is taken along the section line 3B-3B of FIG. 3A and FIG. 3D is taken along the section line 3D-3D of FIG. 3C;

FIG. 3E depicts the movement of the arms of the tissue locator shown in FIGS. 3A-3D, between the retracted and deployed positions;

FIG. 3F is a close-up cross-sectional view of a penetrator receptacle with a cuff disposed therein;

FIG. 4 is a perspective view of a cuff that can be used with embodiments of the present invention;

FIGS. 5A-5D are cross-sectional side and top views of another embodiment of a tissue locator that can be used in the tissue closure devices shown in FIGS. 1 and 2 showing the arms in the retracted position (FIGS. 5A and 5B) and in the deployed position (FIGS. 5C and 5D). FIG. 5B is taken along the section line 5B-5B of FIG. 5A and FIG. 5D is taken along the section line 5D-5D of FIG. 5C;

FIGS. 6A-6D are cross-sectional side and top views of another embodiment of a tissue locator that can be used in the tissue closure devices shown in FIGS. 1 and 2 showing the arms in the retracted position (FIGS. 6A and 6B) and in the deployed position (FIGS. 6C and 6D). FIG. 6B is taken along the section line 6B-6B of FIG. 6A and FIG. 6D is taken along the section line 6D-6D of FIG. 6C;

FIGS. 7A-7C are cross-sectional side views showing the needles before and after engagement with the suture cuffs in the retracted and deployed arms;

FIG. 8 is a perspective view illustrating a suture attachment cuff and an associated barbed needle;

FIG. 9 illustrates a suture cuff and attached suture positioned within a penetrator receptacle;

FIGS. 10A-10C illustrate alternative structures and techniques for avoiding entanglement of the needle with the suture;

FIGS. 11A-G illustrate a method of using a tissue closure device having the tissue locator shown in FIGS. 5A-5D;

FIGS. 12A-D illustrate an alternative method of using a tissue closure device having the tissue locator shown in FIGS. 5A-5D;

FIGS. 13A and 13B illustrate various embodiments of pre-tied knots that can be used with embodiments of the present invention;

FIGS. 14A and 14B are schematic views of a suture bight having a pre-tied knot in accordance with one embodiment of the present invention;

FIGS. 15A-D illustrate one embodiment of a method of attaching a suture to a cuff and releasing the cuff from the arm using a penetrator and then disengaging the penetrator from the cuff;

FIGS. 16A and 16B illustrate an alternative embodiment for releasing the cuff from the arm;

FIGS. 17A and 17B are perspective views of an alternative embodiment of a penetrator tip;

FIGS. 18A through 18C are schematic views of an alternate embodiment of a penetrator and how it can be used to engage with a link;

FIGS. 19A through 19G are schematic views of an alternate embodiment of a penetrator that includes a clamp and ring assembly;

FIG. 20 shows a schematic view of one embodiment of a cuff and link assembly;

FIGS. 21A-21D are cross-sectional side and top views of another embodiment of a tissue locator that can be used in the tissue closure devices shown in FIGS. 1 and 2 showing the arms in the retracted position (FIGS. 21A and 21B) and in the deployed position (FIGS. 21C and 21D). FIG. 21B is taken along the section line 21B-21B of FIG. 21A and FIG. 21D is taken along the section line 21D-21D of FIG. 21C;

FIGS. 22A-22D are cross-sectional side and top views of another embodiment of a tissue locator that can be used in the tissue closure devices shown in FIGS. 1 and 2 showing the arms in the retracted position (FIGS. 22A and 22B) and in the deployed position (FIGS. 22C and 22D). FIG. 22B is taken along the section line 22B-22B of FIG. 22A and FIG. 22D is taken along the section line 22D-22D of FIG. 22C;

FIGS. 23A through 23D are perspective views of a penetrator actuation handle in various modes of operation;

FIGS. 24A and 24B are schematic views, respectively, of a link combination and a corresponding tissue closure formed thereby, according to one embodiment;

FIGS. 25A and 25B are schematic views, respectively, of a link combination and a corresponding tissue closure formed thereby, according to another embodiment;

FIGS. 26A and 26B are schematic views, respectively, of a link combination and a corresponding tissue closure formed thereby, according to another embodiment;

FIGS. 27A and 27B are schematic views, respectively, of a link combination and a corresponding tissue closure formed thereby, according to another embodiment;

FIGS. 28A and 28B are schematic views of a suture net and corresponding tissue closure formed thereby, according to one embodiment;

FIGS. 29A and 29B are schematic views of a suture net and corresponding tissue closure formed thereby, according to another embodiment;

FIGS. 30A and 30B are schematic views of a suture net and corresponding tissue closure formed thereby, according to another embodiments;

FIGS. 31A and 31B are schematic views of a suture link used in conjunction with a suture net and a corresponding tissue closure formed thereby, according to another embodiment;

FIGS. 32A through 32C illustrate a method of using a suture net to close a tissue opening when one portion of the suture net is unusable, according to one embodiment.

DETAILED DESCRIPTION

As used in the specification and appended claims, directional terms, such as "top," "bottom," "up," "down," "upper," "lower," "proximal," "distal," and the like are used herein solely to indicate relative directions and are not otherwise intended to limit the scope of the invention or claims.

The present disclosure provides methods and apparatuses to locate a distal wall of a tissue through an opening in the tissue. Some embodiments of the devices and methods described herein are suitable for closure of vascular punctures or other openings in the tissue. For example, in some embodiments, one or more sutures can be positioned through the tissue adjacent an opening so the opening can be closed using the sutures.

Generally, the apparatuses and methods described herein for tissue location can be used with any type of body tissue. Embodiments used to close openings in tissue can be used with any type of body tissue that has sufficient strength to be held together by sutures. By way of example only, embodiments of the present invention can be used to close openings in tissues that have a wall or membrane function, e.g, pulmonary, intestinal, vascular, urethral, gastric, renal or other wall structures, or in membranes, e.g., amniotic or pericardial membranes. Openings in other types of tissues can also be closed using embodiments of the present invention. Although many types of body tissue can be closed by the methods and apparatuses disclosed herein, the description included herein refers to "vessels" for convenience.

Furthermore, the apparatuses and methods described herein can be used with large and small hole punctures or other openings in the body tissue. By way of example, embodiments of the present invention can be used to close holes from 5 French to 30 French or larger. It may also be possible to close holes of other sizes using embodiments of the present invention.

Turning now to the drawings, FIGS. **1**A and **1**B illustrate a tissue closure device **100** having a housing **102** and a shaft **104** extending therefrom. Housing **102** supports a penetrator actuation handle **106** at a proximal end **108** thereof, and an arm actuation handle **110**. Shaft **104** extends distally from housing **102** from a proximal end **112** to a spaced apart distal end **114**. A flexible, atraumatic monorail guide body **116** can extend distally from distal end **114** of shaft **104**.

A tissue locator **118** is positioned at distal end **114** of shaft **104**. Tissue locater **118** includes a pair of arms **120***a* and **120***b* positioned near distal end **114** of shaft **104**. Arms **120** can move between a low profile, retracted position, in which each arm is substantially aligned along an axis **122** of shaft **104**, to a deployed, expanded position, in which the arms extend laterally away from shaft **104**. The retracted position of arms **120** is shown in FIG. **1**A and the deployed position is shown in FIG. **1**B. The movement of arms **120** between the retracted and deployed positions and back again can be effected by actuation of arm actuation handle **110**. Arm actuation handle **110** can comprise a handle that pivots about a hinged point, as in the depicted embodiment, or can comprise a mechanism that uses a rotary action, a linear action, a cam action, or any other type of action that can move arms **120** between the retracted and deployed positions. The movement of penetrators to and from the deployed arms **120** can be effected by actuation of penetrator actuation handle **106**. Penetrator actuation handle **106** can comprise a handle that linearly moves, as in the depicted embodiment, or can comprise a mechanism that uses a picoting action, a rotary action, a cam action, or any other type of action that can move the penetrators to and from the deployed arms **120**.

FIGS. **2**A-**2**C illustrate another embodiment of a tissue closure device **130** having a modified proximal housing **132**. Similar to tissue closure device **100**, tissue closure device **130** includes a pair of arms **120** that can be moved between the retracted and deployed positions using an arm actuation handle **134**. FIG. **2**C also shows how penetrators **136** can be advanced distally from shaft **104** to arms **120** by depressing a penetrator actuation handle **138**.

Arms **120** and the actuation thereof are illustrated more clearly in the cross sectional views of FIGS. **3**A-**3**E. FIGS. **3**A and **3**B depict arms **120***a* and **120***b* in the retracted position, and FIGS. **3**C and **3**D depict arms **120***a* and **120***b* in the deployed position. FIG. **3**E shows the movement of arms **120***a* and **120***b* between the two positions; the retracted position is shown in solid lines while the deployed position is shown in dashed lines. As can be seen in FIGS. **3**A-**3**E, arms **120***a* and **120***b* are essentially identical except that they are positioned on opposite lateral sides of tissue locator **118** so as to be diametrically opposed to each other.

Each arm **120** of tissue locator **118** extends from a proximal end **150** to a spaced apart distal end **152**. To allow arms **120** to move between the retracted and deployed positions, distal end **152** of each arm **120** is attached to or formed with shaft **104** so as to be pivotable with respect to shaft **104**. That is, each arm **120** is configured to pivot about its distal end **152** to cause proximal end **150** to move radially inward and outward with respect to axis **122**, as shown in FIG. **3**E. This can be accomplished by making at least the distal end **152** of each arm **120** out of a resiliently bendable material. Alternatively, a hinge (not shown) can be attached between distal end **152** of arm and shaft **104** to aid in the pivoting action, if desired.

With reference to FIGS. **3**A and **3**B, each arm **120** has an outer surface **154** and an opposing inner surface **156** extending from distal end **152** to an end face **158** positioned at proximal end **150**. Outer surface **154** faces radially away from axis **122** and can be curved to substantially match the curvature of shaft **104**, if desired. Inner surface **156** faces radially towards axis **122**. If desired, inner and outer surfaces **156** and **154** can be formed so that the thinnest portion (laterally) of each arm **120** occurs at the distal end **152** thereof to aid in the pivoting of the arm thereat.

In the retracted position illustrated in FIGS. **3**A and **3**B, arms **120***a* and **120***b* extend substantially along axis **122** of shaft **104**. If outer surfaces **154** of arms **120** are curved to substantially match the curvature of shaft **104**, tissue locator **118** can essentially form a bridge between the portions of shaft **104** positioned proximally and distally of arms **120**. Tissue locater **118** can have a similar cross-sectional outer surface as shaft **104** when arms **120** are in the retracted position. This can be beneficial when positioning arms **120** through an opening in the tissue before deployment. Advantageously, prior to deployment of arms **120**, tissue locater **118** can have a cross section of about 7 Fr or less. In some embodiments, tissue locater **118** can have a cross section of between 5 and 30 French prior to deployment of arms **120**. In some embodiments, tissue closure device **100** can have a cross-section of about 6 Fr or less for the entire device distal of the proximal end **112** of shaft **104**.

End faces **158** are used to determine the location of the distal surface of the tissue. This can be done by positioning arms **120** through an opening in the tissue until the arms are distal of the tissue, deploying arms **120**, and then pulling tissue locator **118** proximally until end faces **158** contact the distal surface of the tissue. To aid in this, each end face **158** is substantially planar and extends from an outer edge **160** to an inner edge **162**. Outer edge **160** is formed by the intersection of end face **158** with outer surface **154** and inner edge is formed by the intersection of end face **158** with inner surface **156**. End face **158** generally faces proximally and can be substantially orthogonal to outer surface **154** and/or inner surface **156**, or can be at any desired angle with respect to inner or outer surfaces **156** or **154**. In the depicted embodiment, each end face **158** is formed so as to be substantially perpendicular to axis **122** when the corresponding arm **120** is in the deployed position, as shown in FIG. **3**C.

End faces **158** can be of any desired cross-sectional shape. In the depicted embodiment, outer edge **160** of each end face **158** is in the shape of an arc that substantially matches the diameter of shaft **104**. Inner edge **162** extends from either end of outer edge **160** towards axis **122** and is substantially rounded off, as shown in FIGS. **3**B and **3**D. If desired, the innermost portion of each inner edge **162** can alternatively be shaped as a smaller arc of an inner circle, as depicted by dashed lines in FIG. **3**B, to provide more contact with expanders used to move arms **120** between the retracted and deployed positions. Of course, other shapes can also be used.

A penetrator receptacle **164** can be formed on end face **158** of each arm so as to generally face proximally. As shown in the close-up view of FIG. **3**F, a releasable cuff **166** may be disposed within each penetrator receptacle **164**. As such, the penetrator receptacles can also be referred to as cuff pockets. A surface of each receptacle **164** can taper proximally and outwardly to guide advancing penetrators, such as, e.g., needles or other elongated bodies, into engagement with cuffs **166** positioned therein when arms **120** are in the deployed position, as discussed in more detail below.

When in the deployed position, penetrator receptacles **164** can define a lateral width **168** (FIG. **3**D) that can be in a range from about 0.10 inches to about 0.612 inches, with about 0.110 inches to about 0.30 inches being common. Other widths can also be used.

In one embodiment, penetrator receptacles **164** can each include a cuff recess **170** into which cuffs **166** can be positioned. In one embodiment, each cuff recess **170** has a diameter about a centerline of cuff **166** of about 0.0230 inches and a length of about 0.042 inches. In some embodiments, penetrator receptacles **164** can taper outward at an angle between about 20 degrees and about 35 degrees from centerline. A lateral opening or window through the side of arm **120** to each cuff recess may be included to facilitate penetrator and/or cuff positioning during assembly. A protruding collar may be positioned near the proximal end of cuff recess to help keep cuff **166** in position. A slot may also be positioned adjacent penetrator receptacle **164** to receive a suture or other filament, as discussed in more detail below.

Turning to FIG. **4**, cuff **166** can be a roughly cylindrical structure having an axial channel **172** extending therethrough between a proximal end **174** and a distal end **176**. A first slot **178** can be formed at proximal end **174** of cuff **166** to define at least one tab **180**. Tabs **180** can be used to aid in capturing a penetrator inserted into channel **172**, as discussed below. A second slot **182** can be formed at distal end **176** of cuff **166** to define a suture attachment collar **184**. Suture attachment collar **184** can be used to facilitate attachment of a suture or other filament to cuff **166**, also as discussed below. Cuff **166** can be comprised of a resilient material, such as a metal or alloy. For example, in one embodiment, cuff **166** can be comprised of stainless steel.

Returning to FIGS. **3**A and **3**C, tissue locator **118** can also include an arm expansion mechanism to help in moving arms **120** between the retracted and deployed positions. For example, in the depicted embodiment, an arm expansion mechanism **186** can comprise an expander **188** that is moved along axis **122** by an actuator **190**. Actuator **190** can extend proximally from expander **188** through a lumen **192** of shaft **104** or along the outside surface of shaft **104** and can be coupled to arm actuation handle **110** or **134** (FIG. **1**B or **2**B). Actuator **190** can be a rod or the like. Other types of actuators can alternatively be used.

In the depicted embodiment, expander **188** can comprise a substantially conical wedge extending distally from a base **194** to a substantially narrower distal end **196**. When arms **120** are in the retracted position, expander **188** can be positioned within shaft **104** proximal of arms **120**, as shown in FIG. **3**A. Actuation of arm actuation handle **110** or **134** (FIG. **1**B or **2**B) can cause actuator **190** to advance distally, as denoted by arrow **198**, thereby causing expander **188** to also advance distally. Eventually, distal end **196** of expander **188** contacts inner edge **162** of each arm end face **158**. As expander **188** is advanced further distally by actuator **190**, the expander begins to exert an outward force on arms **120** at inner edges **162**. Because distal end **152** of each arm **120** is attached to or formed with shaft **104**, however, distal end **152** cannot be moved radially outward by the exerted force. On the other hand, proximal end **150** of each arm **120** is unattached to shaft **104** and can therefore move radially outward in response to the exerted force, pivoting about distal end **152** to do so. As a result, each arm **120** begins to pivot radially outward about distal end **152**.

Due to the wedge shape of expander **188**, as expander **188** advances further distally, the outward force exerted by expander **188** against inner edges **162** causes each arm **120** to continue to pivot radially outward about distal end **152**. Proximal ends **150** of arms **120** can continue to be pushed radially outward by expander **188** until distal end **196** of expander **188** reaches inner edges **162** of arms **120**. At that point, proximal ends **150** of arms **120** are in the deployed position shown in FIGS. **3**C and **3**D. As noted above, in the deployed position, arms **120** can be used to locate the distal wall of the tissue through the tissue opening, as discussed in more detail below.

To move arms **120** back to the retracted position shown in FIGS. **3**A and **3**B, arm actuation handle **110** or **134** (FIG. **1**B or **2**B) can be moved back to its original position, thereby causing actuator **190** to retract proximally. This causes expander **188** to also move proximally, thereby allowing the proximal end **150** of arms **120** to move radially back towards axis **122**. To aid in moving arms **120** back to the retracted position, each arm **120** can be made of a resilient material that biases the arm towards the retracted position. For example, arms **120** can be made of a resilient polymer, metal, alloy, or the like. A shape memory alloy, such as, e.g., a nickle titanium allow, commonly known as nitinol, can also be used. Alternatively, a biasing element, such as, e.g., a spring, can be attached between arms **120** to bias the arms to the retracted position.

In an alternative embodiment, expander **188** can be threaded. In that embodiment, rotation of actuator **188** about axis **122** can cause expander **188** to rotate. Due to the threaded connection with inner edges **162**, this can cause expander **188** to move distally with respect to arms **120**, thereby rotating arms **120** to the deployed position. If desired, to make the threaded connection stronger, each inner edge **162** can also include a portion of a thread that mates with the thread on expander **188**, as indicated by the dashed lines shown on FIG. **3**B. To actuate the threaded expander, a rotating arm actuation handle can be used.

FIGS. **5**A-**5**D show an alternative embodiment of a tissue locater **200** that allows for further lateral movement of the arms than tissue locater **118**. Tissue locater **200** includes arms **202***a* and **202***b* that are substantially longer than arms **120**, with an inner surface **204** of each arm being shaped to include a recess **206** between proximal and distal ends **150** and **152**, as shown in FIG. **5**A. Each recess **206** extends from a proximal end **208** distally outward to an outer edge **210** and then inward to an inner edge **212** at a distal end **214**. Inner edge **212** is closer to axis **122** than is outer end **210**. The recesses **206** of arms **202** combine to generally form a cavity **216**. Recesses **206** are shaped so that when arms **202** are in the retracted position, expander **188** can be positioned within cavity **216**, as shown in FIG. **5**A.

Similar to the embodiment described above, as expander **188** moves distally, the outer surface thereof can contact and move inner edges **212** laterally outward, thereby causing proximal ends **150** of arms to pivot radially outward about distal ends **152** until arms **202** are fully deployed, as shown in FIGS. **5**C and **5**D. Because inner edges **212** of inner surface **204** are positioned distally of proximal end **150**, and because arms **202** are substantially longer than arms **120**, proximal ends **150** of arms **202** are moved substantially further radially outward when deployed than are arms **120** (compare FIGS. **5**C and **5**D to FIGS. **3**C and **3**D).

Similar to the embodiment discussed above, expander **188** can be substantially conically shaped. Alternatively, expander **188** can be substantially cylindrically or rectangularly shaped as long as cavity **216** is generally shaped to receive expander therein. Other expander shapes may also be possible.

FIGS. **6**A-**6**D show an alternative embodiment of a tissue locater **230** that uses an expander **232** that is moved proximally instead of distally to deploy the arms. Similar to the tissue locaters discussed above, tissue locater **230** also includes arms **234***a* and **234***b* having penetrator receptacles **164** on proximal end faces **158** thereof for receiving cuffs. On arms **234**, a lower portion **236** of each inner surface **238** extends inward toward axis **122** as inner surface **238** extends proximally from distal end **152** of arm **234**, so as to generally form a ramp, as shown in FIG. **6**A.

Unlike the expanders discussed above, expander **232** can be initially positioned distal of the distal end **152** of arms **234** when arms are in the retracted position, as shown in FIG. **6**A. As expander **232** is withdrawn proximally, the outer surface thereof can contact the bottom portion of ramp **236** of each arm **234**. As expander **232** is withdrawn further proximally, expander **232** begins to exert an outward force on arms **234** at ramps **236**. As expander **232** is withdrawn further proximally, the outward force exerted by expander **232** on ramps **236** causes proximal ends **150** of arms **234** to pivot outward about distal end **152** until arms **234** are fully deployed, as shown in FIGS. **6**C and **6**D. As such, although various components of tissue locator **230** may be different than tissue locators **118** and **200**, discussed above, the result is the same; proximal ends **150** of arms are caused to move from the retracted position to the deployed position by actuation of the actuator.

Expander **232** is shown in the depicted embodiment as being substantially cylindrical. However, similar to the expanders discussed above, expander **232** can be substantially conical or rectangular if arms are modified accordingly. Other expander shapes may also be possible.

Turning to FIGS. **7**A-**7**C, which shows tissue locator **200**, cuffs **166** can be used in conjunction with penetrators **136** to help position a loop of suture or other filament **264** across a tissue opening **250** to aid in closing the opening. Each penetrator **136** can comprise a substantially rigid elongated shank **252** that extends to a distal tip **254**. Penetrator **136** can also include means for attaching the penetrator to the cuff. The means for attaching can provide a permanent attachment or a removable attachment, as discussed in more detail below. In the depicted embodiment, penetrator **136** comprises an elongated needle and the means for attaching the penetrator to cuff **166** comprises a barbed tip **256** (FIG. **8**) that provides a permanent attachment to cuff **166**. Penetrators **136** can be initially positioned within channels or lumens **258** defined in shaft **104** to carry the penetrators, as shown in FIG. **7**A. Likewise, arms **202** (**202***a* and **202***b*) can be initially positioned in the retracted position, as shown in FIG. **7**A. Before using penetrators **136**, arms **202** should be moved to the deployed position shown in FIG. **7**B. This can be done by manipulating arm actuation handle **110**, as discussed above.

As shown in FIG. **7**A, penetrator guides **260** can be positioned at the distal end of lumens **258** to laterally deflect penetrators **136** outward as penetrators **136** are moved distally so penetrators **136** can extend laterally to cuffs **166** of arms **202** when arms **202** are in the deployed position. This lateral deflection of penetrators **136** can allow the use of a small diameter shaft **104**, while still encompassing sufficient tissue within the suture loop on opposite sides of the tissue opening so as to effect hemostasis when the suture loop is tightened and secured.

In some embodiments, shaft **104** can comprise an outer casing of a biocompatible material such as stainless steel, carbon fiber, nylon, another suitable polymer, or the like. Penetrator guides **260** may be defined at least in part as lumens formed within the casing of a polymeric material such as nylon or the like. In some embodiments, shaft **104** may comprise a carbon-fiber filled nylon, or carbon fiber filled with an alternative material.

As shown in the depicted embodiment, an end **268** of suture loop **264** can be attached to each cuff **166**. Opposite ends of the same suture can be secured to different cuffs **166**, as in the depicted embodiment, or ends of different sutures can be used.

In one embodiment, suture **264** can comprise a continuous filament with one end **268** of the suture being attached to cuff **166** in penetrator receptacle **164** of one arm **202***a* and the other end **268** of the suture being attached to cuff **166** in penetrator receptacle **164** of the opposite arm **202***b*. An intermediate portion **270** of suture **264** between the ends **268** may extend proximally into shaft **104**. In one embodiment, intermediate portion **270** can extend along a suture lumen of shaft **104** to proximal housing **102** or beyond. Alternatively, the intermediate portion **270** of suture **264** between the ends **268** may extend distally within guide body **116** or may be positioned external to shaft **104**. In still further alternatives described below, a short length of suture or some other flexible filament **264** may extend substantially directly between the penetrator receptacles in the two arms.

To use penetrators **136** to help close tissue opening **250**, arms **202** of tissue closure device **200** should be positioned through opening **250** and then moved to the deployed position shown in FIG. **7**B. This can be done by manipulating arm actuation handle **110**, as discussed above. As arms **202** are moved to the deployed position, ends **268** of suture **264** also move outward due to the attachment of suture **264** to each cuff **166**.

Upon actuation of penetrator actuation handle **106** (see FIGS. **1** and **2**), penetrators **136** move distally and extend laterally from shaft **104** to securely engage with cuffs **166**, as shown in FIG. **7**C. Specifically, penetrators **136** advance from fixed penetrator guides **260**, and are laterally directed into cuffs **166** by receptacles **164**.

In one embodiment, penetrator **136** comprises an elongated needle having a barbed end **256** defining a recessed engagement surface **262**, as shown in FIG. **8**. Channel **172** of cuff **166** can receive barbed end **256** of needle **136** therein. Tabs **180** can be resiliently biased inward into channel **172**. As needle **136** advances into cuff **166**, barbed end **256** resiliently displaces tab **180** clear of channel **172** so as to allow the barbed end to pass axially into cuff **166**. Once barbed end **256** is disposed axially beyond tab **180**, tab **180** can resiliently flex back into channel **172**, thereby capturing needle **136** by engagement between tab **180** and recessed surface **262**. As each tab **180** can hold cuff **166** in place on needle **136**, the use of more than one tab can increase the reliability of the system. For example, three tabs **180** can be provided on cuff **166**, as illustrated in FIG. **4**. Once needle **136** has been secured to cuff **166**, the cuff can be withdrawn proximally from arm **234** by withdrawing needle **136** proximally back toward shaft **104**. Other types of penetrators besides needles can also be used with cuff **166**, as discussed below.

Returning to FIG. **7**C in conjunction with FIG. **8**, each cuff **166** can be generally configured to facilitate withdrawal of itself (and any attached suture or filament **264**) along with penetrator **136** axially through the tissue wall **266** along the penetrator path. As such, penetrator **136** can comprise an elongated shank having a cross-sectional width of between about 0.010 inches and about 0.020 inches, with other widths being possible. Engagement surface **262** formed by barb **256** can have a protruding length of between about 0.002 inches and about 0.005 inches, with other lengths being possible.

As shown in FIG. **8**, cuff **166** can have a cross-sectional size roughly corresponding to or slightly larger or smaller than penetrator **136**. In one embodiment, cuff **166** can have an outer lateral width of between about 0.014 inches and 0.025 inches, and an axial length of between about 0.035 inches and 0.050 inches. Channel **172** can be sized to receive at least a portion of needle **136**, and can generally have a width of between about 0.010 inches and 0.020 inches, with other widths also being possible. In the exemplary embodiment, penetrator **136** has a diameter of about 0.020 inches, while the cuff comprises a tube having an outer diameter of about 0.020 inches, an inner diameter of about 0.016 inches, and an overall length of about 0.047 inches. In some embodiments, the diameter of cuff **166** is based primarily on the diameter of suture **264** attached thereto. Weeping of blood can occur through the tissue hole created by penetrator **136** if the hole is substantially larger than the suture. As such, greater diameters can be used for cuff **166** and penetrator **136** if a suture of a correspondingly greater diameter is used.

Penetrator **136** can have a length of between about 5.0 inches and 6.0 inches, with other lengths also possible. Penetrator **136** can be sufficiently stiff to be advanced in compression through the tissue wall (and adjacent tissues, if necessary) for up to about 0.5 inches when supported in cantilever. Greater distances may also be possible. Penetrator **136** can also be substantially flexible to be laterally deflected within shaft **104** by penetrator guide **260**, as discussed above. Penetrator **136** can be comprised of a high strength metal, such as, e.g., stainless steel. Other materials can also be used.

Cuff **166** can also comprise a flexible material to allow tab **180** to flex out of the way of barbed end **256**, and to resiliently rebound and engage recessed surface **262**, as discussed above. In one embodiment, barbed end **256** can have a diameter of about 0.015 inches, with the diameter of the penetrator decreasing to about 0.008 inches proximally of the barb so as to define recessed engagement surface **262**.

As noted above, an end **268** of suture or other filament **264** can be attached to each cuff **166**. In the embodiment depicted in FIG. **8**, the end **268** of suture **264** is secured to the distal end of cuff **166** using suture collar **184**. Collar **184** may be crimped about suture **264** to mechanically affix the suture to cuff **166**. In addition and/or instead of mechanical crimping, the end of the suture may be bonded to cuff **166** using an adhesive, heat, fasteners, knots, or the like. In one embodiment, one or both ends of the suture is enlarged to prevent the end from passing completely through the cuff. Other types of securing devices or methods can also be used. Opposite ends of the same suture can be secured to different cuffs **166**, as in the embodiment depicted in FIGS. **7A-7C**, or ends of different sutures can be used.

By being secured to cuff **166**, the end **268** of suture **264** can also be withdrawn proximally from arm **202** when the cuff is withdrawn proximally by penetrator **136**. As such, as cuffs **166** and associated portions of suture **264** are releasably supported in arms **202**, needles **136** can be withdrawn proximally so as to draw cuffs **166** and attached suture ends **268** from arms **202** proximally into shaft **104**. By extending axially from cuff **166** opposite the open end of channel **172**, drag may be minimized when the suture is drawn proximally along the penetrator path.

As discussed above, cuffs **166** and suture **264** can be withdrawn proximally from penetrator receptacles **164** by penetrators **136**. Turning now to FIG. **9**, to avoid entanglement of suture **264** with penetrators **136**, a slot **272** can be formed in each arm **202** so as to extend laterally and proximally from penetrator receptacle **164**. Slot **272** can be sized to receive suture **264** as suture **264** extends from cuff **166**. As penetrators **136** pull cuffs **166** axially from penetrator receptacles **164**, suture **264** can be pulled from slots **272** and free from arms **202**. Bending of suture **264** within suture slot **272** can also help hold cuff **166** in penetrator receptacle **164**. If desired, slot **272** can be sized to have a smaller cross-section than barbed tip **256** so that the barbed tip is unable to enter slot **272**, thereby avoiding entanglement between penetrator **164** and suture **264**.

A variety of other features may be included in the arms, penetrator receptacles, and/or penetrators to avoid tangling of the penetrators in the suture as the penetrators are directed to the cuff. For example, as illustrated in FIG. **10A**, a moveable flap **274** may extend over slot **272** so that the advancing penetrator can slide along flap **274** toward the cuff, rather than entering slot **272** and engaging suture **264** directly. Flap **274** may be affixed along one side of slot **272**, with the other side of flap **274** flexing into receptacle **164** to release suture **264** from slot **272** when the cuff and suture **264** are withdrawn by the penetrator.

In an alternative mechanism for avoiding entanglement of the penetrator with the suture, slots **272** of penetrator receptacles **164** can extend substantially tangentially to the surface of the receptacle. As a result of this tangential arrangement, a penetrator entering receptacle **164** can be directed toward cuff **166** contained therein, but does not enter and advance within the tangential slot **272** so as to become entangled with the suture. Slots **272** may optionally extend laterally through the arm so that the loop of suture can be pulled from one side of the shaft **104** without interference.

Another alternative mechanism for avoiding entanglement between the suture and the penetrator is illustrated in FIGS. **10B** and **10C**. A two-part penetrator **136*i*** can include an outer sheath **276** and an inner core **278**. These parts of the penetrators can initially advance together into the receptacles with penetrator core **278** retracted so that the penetrator presents a smooth tapered tip, as illustrated in FIG. **10B**. If desired, the combined tip can be larger in diameter than the slot containing the suture. Once two-part penetrator **136*i*** is fully positioned within the penetrator receptacle, penetrator core **278** may be extended axially to expose barbed tip **256** and recessed engagement surface **262**, as shown in FIG. **10C**, and to secure the penetrator to the cuff within the penetrator receptacle.

A first method of using a tissue closure device having a tissue locator to close an opening in tissue will now be explained with reference to FIGS. **11A-11G**. For purposes of discussion, the method will be set forth with reference to tissue locator **200**. However, it is appreciated that the other tissue locators discussed or envisioned herein can alternatively be used in this or any of the methods presented herein. Initially, arms **202** are in the retracted position with cuffs **166** being positioned within penetrator receptacles **164**, and penetrators **136** are withdrawn within shaft **104** proximal of arms **202**, as shown in FIG. **7A**. A length of suture **264** is provided with ends **268** of suture **264** attached to each cuff **166** and the intermediate section **270** of suture **264** extending into shaft **104** proximal of arms **120**. Alternatively, intermediate section of suture can extend into shaft **104** or guide body **116** distal of arms **120**, or can be positioned external to shaft **104**, as discussed above.

Tissue locater **200** can be used to help close an opening in tissue, such as an incision in a blood vessel. To do so, the distal end of shaft **104** is advanced distally through a tissue tract **300** and through the opening **250** in the vessel wall **266** while the arms are in the retracted position, as shown in FIG. **11A**. This can be done in a number of ways. For example, after an endovascular procedure, a guide wire **302** and a guide body that have been positioned through the opening **250** in vessel wall **266** can be used. Shaft **104** is advanced until tissue locater **200** has advanced through opening **250** and into the blood vessel **304** far enough that the proximal ends **150** of arms **202** are positioned distal of vessel wall **266**, as shown in

FIG. **11**B. Shaft **104** can include a bleed-back lumen, as is known in the art, to notify the operator that arms **202** have been advanced far enough for deployment.

Once arms **202** are positioned within the vessel lumen **304** (i.e., distal of vessel wall **266**), arms **202** can be deployed and used to "locate" the inner surface **306** of vessel wall **266** surrounding opening **250**. To do so, the expander is moved to contact and produce a laterally outward force on arms **202** by actuation of the arm actuation handle, as discussed above. This causes the proximal ends of arms **202** to rotate radially outward to the deployed position in the manner discussed above, on the distal side of the vessel wall **266**, as shown in FIG. **11**C. Using tissue locator **200**, the expander is moved distally when actuated, as discussed above. It is appreciated that with other embodiments of tissue locators, the expander may instead be moved proximally to provide the laterally outward force for moving the arms to the deployed configuration, as discussed above.

Once arms **202** have been fully deployed, shaft **104** can be gently pulled proximally until the penetrator receptacles **164** formed on arm faces **158** are drawn proximally against the inner surface **306** of vessel wall **266** on opposite sides of opening **250**, as shown in FIG. **11**C. See also FIG. **7**B. Not only do arms **202** help to accurately position the penetrator receptacles on the distal surface **306** of the tissue wall **266**, they also help to position the penetrator guides at a predetermined proximal distance from the tissue.

Once the arm faces are drawn proximally against the inner surface **306** of vessel wall **266**, penetrators **136** can be extended to arms **202**, as shown in FIG. **11**D. To do this, penetrators **136** are advanced distally and laterally from channels or lumens in shaft **104** through penetrator guides by actuation of the penetrator actuation handle, as discussed above.

The distal tips of penetrators **136** form penetration paths **308** in vessel wall **266** on opposite sides of opening **250** as penetrators **136** advance distally therethrough. As the distal ends of penetrators **136** advance to arms **202**, the tapering surfaces of the receptacles help to push penetrators **136** into alignment with the cuffs in arms **202** so as to overcome any unintended deflection of penetrators **136** by surrounding tissue **310** or vessel wall **266**. This ensures that the means for attaching each penetrator **136** to the corresponding cuff engages the cuff within each receptacle, as discussed above, thereby coupling the ends **268** of suture **264** to the penetrators. In the present method, the means for attaching the penetrator to the cuff comprises the barbed tip to provide a permanent attachment between the penetrator and the cuff.

As discussed above, the middle portion **270** of suture **264** can be positioned within a shaft **104** proximal of arms **202**. Alternatively, the suture loop can instead extend distally from arms in a lumen of shaft **104** or guide body, can be routed through the arms, and/or can be positioned external to the shaft and guide body. Other suture paths can also be used. Regardless, suture **264** should be configured to pull free of the tissue closure device between the ends of the suture to form a continuous loop across opening **250**. The amount of suture **264** between arms **202** can vary.

Penetrators **136** can then be used to pull suture **264** proximally through vessel wall **266**, as shown in FIG. **11**E. To do so, penetrators **136** are withdrawn proximally through penetration paths **308** in vessel wall **266** by moving penetrator actuation handle **106**. Due to the secure engagement of penetrators **136** and suture **264** to cuffs **166**, the withdrawal of penetrators **136** causes cuffs **166** and the ends **268** of suture **264** to also be drawn proximally through vessel wall **266** along penetrator paths **308** formed by penetrators **136**. As ends **268** of suture **264** move proximally through vessel wall **266**, a portion of the intermediate section **270** attached to ends **268** is also pulled proximally through penetrator paths **308**.

After the ends **268** of suture **264** have been withdrawn proximally through vessel wall **266** and into shaft **104** by penetrators **136**, tissue locater **200** can be removed. To do so, arms **202** are moved back to the retracted position shown in FIG. **11**F by moving the expander using arm actuation handle **110**. This causes the expander to no longer produce a lateral outward force on arms **202**, which allows the proximal ends of arms **202** to rotate inward to the retracted position. If needed, tissue closure device **200** can be moved slightly distally away from inner surface **306** of vessel wall **266** before retraction of arms **202** so the arms can move to the retracted position more easily. Using tissue locator **200**, the expander is moved proximally to allow arms **202** to rotate back to the retracted position. It is appreciated that with other embodiments of tissue locators, the expander may instead be moved distally to allow the arms to rotate back to the retracted position, as discussed above.

With arms **202** in the retracted position, shaft **104** can be withdrawn proximally through tissue tract **300** and removed therefrom. This causes tissue locater **200** to also move proximally back through opening **250** to be withdrawn from tissue tract **300**. The withdrawal of tissue closure device **200** also causes the ends **268** of the suture loop **264**, which are still secured to needles **136**, to continue to be proximally withdrawn. As the suture ends **268** are withdrawn, more of the intermediate section **270** of the suture **264** is pulled proximally through penetrator paths **308** on both sides of opening **250**. If any of the intermediate portion **270** of suture **264** is originally positioned proximal of vessel wall **266**, that portion passes distally through opening **250** before being pulled back proximally through penetrator paths **308** in vessel wall **266**.

Once shaft **104** has been withdrawn sufficiently, suture **264** can be used to close opening **250**. To do so, ends **268** of the suture **264** can be grasped by the operator and pulled proximally to pull the remaining suture loop **264** proximally through penetrator paths **308** on the opposite sides of opening **250** to close the opening, as shown in FIG. **11**G. A knot or closure device can then be used to secure suture **264** to allow the closure of opening **250** to become permanent, as is known in the art.

FIGS. **12**A-**12**D show an alternative, second, method of using tissue locator **200** to close the tissue opening. In the alternative method, rather than pulling the two opposite ends of an extended loop through the needle paths and proximally out the tissue tract for tying, tissue closure device **200** advances a single end of suture distally along one needle path, across the opening, and then proximally out along the other needle path.

Similar to the first method, shaft **104** is advanced through opening **250** until the proximal ends **150** of arms **202** are positioned distal of the vessel wall **266**, whereupon arms **202** are deployed and moved into contact with the inner, or distal, surface **306** of vessel wall **266** surrounding opening **250**, as shown in FIG. **12**A. Also similar to the first method, each penetrator receptacle **164** contains a cuff **166** having attached thereto an end **268** of suture or filament **264**. However, instead of two ends of a long suture being attached to the cuffs, suture or connecting filament **264** is short and spans substantially directly between penetrator receptacles **164** to attach to cuffs **166**, as shown in schematic in FIG. **12**A. As such, connecting suture or filament **164** forms a link between cuffs **166**.

Similar to the first method, each penetrator **136** includes means for attaching the penetrator to the cuff. However, while one of the penetrators includes a means for attaching that is permanent (e.g., the barbed tip), the other penetrator includes a means for attaching that is releasable. For ease of description, the penetrator having the means for permanent attachment will be referred to as the "first" penetrator and the penetrator having the means for releasable attachment will be identified as the "second" penetrator herein and the identifiers thereof will be respectively differentiated with an "a" and a "b" appended to the identifier. Thus, the first penetrator and second penetrators **136** will be respectively identified as **136***a* and **136***b*. The cuffs, penetrator receptacles, penetrator paths, etc. associated with each penetrator will likewise be referred to as "first" and "second" cuffs, penetrator receptacles, penetrator paths, etc and be differentiated in the same manner (i.e., with an "a" or "b" appended to the identifier) as the penetrators.

To facilitate separation of the second penetrator **136***b* from the second cuff **166***b*, second penetrator **136***b* includes a detachable coupling structure that allows penetrator **136***b* to separate from the second cuff **166***b* when the penetrator is withdrawn therefrom. For example, in the depicted embodiment, the distal end of second penetrator **136***b* comprises a detachable tip **314**.

A suture loop **316** having two ends **318** and **320** is positioned within or proximal of shaft **104**, as shown in schematic. The first end **318** of suture **316** is releasably attached to second penetrator **136***b* using the detachable coupling structure so that suture **316** can separate from second penetrator **136***b* when second penetrator **136***b* is withdrawn from second cuff **166***b*. For example, in the depicted embodiment, the first end **318** of suture **316** is attached to detachable tip **314**. Second penetrator **136***b* may be hollow so that suture **316** may extend proximally within the hollow penetrator where the penetrator has an open channel along its length, may exit the hollow penetrator just proximally of detachable tip **314**, or may be disposed alongside a solid penetrator.

Similar to the first method, both penetrators **136** are advanced distally through tissue wall **266** to become attached to cuffs **166**, as shown by arrows **322** in FIG. **12**B. Because of its attachment to second penetrator **136***b*, the first end **318** of suture **316** is also advanced proximally through tissue wall **266** and secured to second cuff **166***b* along with second penetrator **136***b*.

When penetrators **136***a* and **136***b* are subsequently withdrawn proximally from arms **202**, as indicated by direction arrows **324** in FIG. **12**C, suture **316** advanced through tissue wall **266** with second penetrator **136***b* remains attached to second cuff **166***b* with the detachable tip. First cuff **166***a* remains secured to first penetrator **136***a*, as in the first method, and is withdrawn proximally therewith. As link **264** extends between cuffs **166***a* and **166***b*, and as detachable tip **314** can pull free of second penetrator **136***b* when the penetrators are withdrawn, this effectively couples first penetrator **136***a* to first end **318** of suture **316**.

Thus, as first cuff **166***a* is withdrawn proximally through first penetrator path **308***a* as indicated by directional arrow **324**, link **264** between cuffs **166***a* and **166***b* is drawn across the tissue opening, as indicated by directional arrow **326**, and also withdrawn proximally through first penetrator path **308***a*. Because of its attachment to link **264**, second cuff **166***b*, along with suture **316** now attached thereto, are also drawn across the tissue opening, as indicated by directional arrow **328**.

As shown in FIG. **12**D, as the first and second penetrators are further withdrawn proximally, second cuff **166***b* is withdrawn proximally through first penetrator path **308***a* and out of the body, as indicated by directional arrow **330**, by virtue of the attachment of second cuff **166***b* to link **264**. As a result, suture **316**, which is attached to second cuff **166***b*, is pulled distally through second penetration path **308***b*, as indicated by directional arrow **332**, across the tissue opening, as indicated by directional arrow **334**, and then back proximally through first penetration path **308***a*, as indicated by directional arrow **336**.

As a result, rather than pulling both ends of an extended loop through the penetrator paths and proximally out the tissue tract for tying as is done in the first method, a single end of suture attached to the second cuff advances distally through the second penetrator path, across the tissue opening, and then proximally along the first penetrator path as the penetrators are withdrawn.

Once the first end **318** of tissue **316** has been withdrawn proximally through first penetration path **308***a*, arms **202** can be moved to the retracted position and tissue closure device **200** can be removed from the tissue tract. A knot or closure device can then be used to secure the suture **316** to allow the closure of the tissue opening to become permanent.

The second method is especially useful for using a pre-tied knot to close the tissue opening. For example, turning to FIG. **13**A, a bight **340** of suture **316** can be releasably attached to the shaft encircling the opening of penetrator guide **260** (see FIG. **12**A) of the fixed tip penetrator. The bight **340** of suture **316** may be releasably disposed within a slot of the shaft, may be temporarily held in place by a weak adhesive or coating, or the like. The second end **320** of suture **316** can extend proximally along the shaft and can also be releasably held along the shaft, if desired.

Bight **340** can define a knot when the first end **318** of suture **316** passes therethrough, as can be understood with reference to FIGS. **12**A-**12**D. Bight **340** can include one or more loops, and can be pre-arranged so as to define a square knot using the general layout illustrated in FIG. **13**A, a cinch knot using the general layout illustrated in FIG. **13**B, or a variety of known or new surgical knots.

The knot can be completed by pulling second penetrator **136***b*, short suture **264**, and first end **318** of suture **316** (together with cuffs **166***a* and **166***b* and detachable first penetrator tip **314**) proximally through bight **340**. Second end **320** of suture **316** can be pulled to free bight **340**, and the ends **318** and **320** of suture **316** can be tightened and the tissue closure device removed to provide permanent hemostasis.

In an alternative embodiment of tissue closure device **200**, a slot can be included, distal of arms **202**, that includes a passage that defines a suture bearing surface through which link **264** and second cuff **166***b* can pass. Instead of link **264** attaching directly between first and second cuffs **166***a* and **166***b* across the tissue opening, an intermediate portion of the link can be positioned within the passage. Then, when the penetrators are withdrawn proximally, the link, the second cuff, and the suture can all pass through the passage before being withdrawn proximally through the first penetrator path.

Using a passage can provide some unique benefits. For example, the suture bearing surface can bear forces placed on the suture during suturing. As such, the suture-bearing surface can minimize forces placed on an incision during incision tensioning, thereby minimizing the possibility of damaging tissue immediately surrounding the incision.

FIGS. **14**A and **14**B show one embodiment of a suture bight **342** that can be used with suture link **264**. FIG. **14**A depicts suture bight **342** in a pre-deployed state and FIG. **14**B depicts suture bight **342** in a deployed state. As the suture link **264** and the suture **316** move, a pre-tied suture knot **344** can also move in the same direction as the suture loop **264**, as indicated by directional arrow **346**. Suture loop **264** can continue to move pre-tied suture knot **344** towards the incision until suture **316** and pre-tied suture knot **344** close the incision formed in the vessel wall.

Suture **316** can be arranged to provide the pre-tied knot **344** that automatically travels down from the shaft of the tissue closure device where the knot can be stored prior to delivery to the tissue wall. The suture loop **264** can serve to pull knot **344** down a rail portion **348** of suture **316** during deployment. If desired, the ends **318** and **320** of suture **316** can be differentiated from each other so the operator can distinguish them and pull the correct end to advance and tighten the knot.

FIGS. **15**A-D illustrate a method of attaching suture **316** to cuff **166** and releasing cuff **166** from arm **202** using penetrator **136**. As such, the illustrated method can be used to attach suture **316** to the second cuff **166***b* using second penetrator **136***b* in the second method discussed above. Penetrator **136** may be any type of structure capable of penetrating the wall of a lumen, such as an artery, a blood vessel, or the like. In addition to the penetration capability, the penetrator may incorporate a hollow tube capable of holding suture. Examples of such structures may include a hypodermic needle or the like. As discussed above, in many embodiments the tissue locator can store penetrator **136** within its shaft, as shown in FIG. **7**A. As previously described with reference to FIGS. **2**A through **2**C, a user can deploy a handle of the suturing device to deploy penetrator shank **252** and its corresponding penetrator tip **256**. During deployment, penetrator shank **252** and penetrator tip **256** penetrate the lumen wall **266** immediately surrounding the incision or other tissue opening, as shown in FIG. **15**A.

Penetrator **136** is advanced through lumen wall **266** until penetrator tip **256** engages with cuff **166**, which is positioned within cuff recess **170**. Once penetrator tip **256** engages with cuff **166**, the penetrator can be further advanced so that penetrator tip **256** advances cuff **166** further into arm **202**, as shown in FIG. **15**B. As may be seen with reference to FIG. **15**B, cuff **166** can be thereby dislodged out of pocket **170** (FIG. **15**A) and into a lumen in arm **202**. Once cuff **166** has been dislodged from pocket **170**, a push mandrel **350** can be used to detach penetrator tip **256** from penetrator shank **252** as shown with reference to FIG. **15**C.

FIG. **15**C illustrates the detachment of penetrator tip **256** from penetrator shank **252** in accordance with one embodiment of the present invention. Upon engagement of penetrator tip **256** with cuff **166**, push mandrel **350** is further advanced such that it contacts proximal surface **262** of penetrator tip **256**, and further still until penetrator tip **256** detaches from penetrator shank **252**.

As shown in FIG. **15**D, after penetrator tip **256** detaches from penetrator shank **252**, penetrator shank **252** retracts from penetrator tip **256** and cuff **166**, leaving suture **316** attached to cuff **166**. Then, when suture link **264** is pulled across the tissue opening by the penetrator on the other side of the tissue locator (not shown), cuff **166** and attached suture **316** will follow, as discussed in the second method above.

FIGS. **16**A and **16**B illustrate an alternative embodiment for releasing cuff **166** from arm **202**. In this embodiment, arm **202** includes link passageway **352** through which link **264** passes. After penetrator shank **252** engages penetrator tip **256** with cuff **166**, penetrator shank **252**, during retraction from arm **202**, removes cuff **166** and penetrator tip **256** from the arm. The force holding penetrator tip **256** on penetrator shank **252** overcomes the force holding cuff **166** in cuff pocket **170**. Once cuff **166** clears arm **202** and attains the orientation shown with reference to FIG. **16**B, the previously described push mandrel (not shown) can detach penetrator tip **256** from penetrator shank **252**. Upon detachment of penetrator tip **256** from penetrator shank **252**, cuff **166** and attached suture **316** are free to be pulled across the tissue opening by link **264**, as discussed above. In an alternate embodiment, cuff **166** and penetrator tip **256** may be pulled off elongated shank **252** by tension in link **264**. Alternatively, cuff **166** and penetrator tip **256** may be detached from penetrator shank **252** before being removed from cuff pocket **170**.

Alternative cuff configurations may be used that facilitate engagement of penetrator bodies **252** with link **264**. For example, FIG. **17**A illustrates a perspective view of an alternative embodiment of a penetrator tip **354** that can be used with cuff **166**. In this embodiment, penetrator tip **354** includes windows **356** with proximal facing mating surfaces **358** which engage with tabs **180** of cuff **166** when penetrator tip **354** engages with cuff **166**, as shown in FIG. **17**B. As such, a user can detach penetrator shank **252** from penetrator tip **196** with push mandrel **350** after engagement of penetrator tip windows **356** with cuff tabs **180**, as discussed with reference to penetrator tip **256** and cuff **166**.

FIGS. **18**A-C show an alternative method of coupling penetrator shank **252** with link **264**. In this embodiment, penetrator shank **252** includes a loop **360** which engages with link **264** as penetrator shank **252** enters arm **202**. To facilitate the engagement, link **264** is constructed of a resilient material capable of flexing in response to loop **360** contacting link **264**, such as polypropylene or any other material having spring-like characteristics.

As shown in FIG. **18**A, penetrator shank **252** moves distally into arm **202** in the direction indicated by directional arrow **362** until loop **360** comes into contact with an end **268** of link **264**. When loop **360** contacts the end **268**, loop **360** moves the end **268** in the direction indicated by directional arrow **364**. As penetrator shank **252** continues to distally advance, loop **360** continues to move the end **268** of link **264** in the direction **364** until loop **360** advances beyond the end **268** of link **264**.

As noted above, link **264** can be constructed of a material having spring like properties. As such, when loop **360** advances beyond the end **268** of link **264**, the resilient properties of link **264** move the end **268** in the direction indicated by directional arrow **368** in FIG. **18**B. The end **268** of link **264** moves in the direction **368** such that the end **268** of link **264** moves into loop **360**, as shown in FIG. **18**B. Once the end **268** of link **264** moves into loop **360**, loop **360** can be retracted into the penetrator shank **252** in the direction indicated by directional arrow **370**. In some embodiments the end **268** of link **264** also moves into penetrator shank **252** with loop **360**. In some embodiments, the end **268** of link **264** remains outside of penetrator shank **252**.

As shown in FIG. **18**C, as loop **360** moves in the direction **370**, loop **360** clamps link **264** against a surface **372** of the elongate shank **252**. As a result, during retraction of the penetrator from arm **202**, link **264** remains engaged with penetrator shank **252**. As penetrator shank **252** and loop **360** retract from arm **202**, loop **360** pulls link **264** through penetrator path **308**, as shown in FIG. **18**C. While loop **360** pulls link **264**, cuff **166** (not shown) and the suture **152** (not shown) also can move through penetrator path **308** in order to enable closure of a tissue opening.

In another embodiment, the suturing device **150** may also employ a clip and ring assembly **374** to couple the penetrator bodies **252** with link **264**, as shown with reference to FIGS. **19**A-G. FIGS. **19**A and **19**B illustrate clip and ring assembly **374** in an attached configuration. Clip and ring assembly **374** comprises a clip **376** and a ring **382** that engages with clip **376**. Each clip **376** can include flexible arms **378** and a passageway **380** between the arms **378**. Ring **382** can have a circular configuration as shown with respect to FIG. **19**B. Initially, the clip **376** can be incorporated into penetrator shank **252** in place of penetrator tip **256** or needle tip **314**. Alternatively, clip **376** can be initially positioned within penetrator **252** and extendable therefrom, as shown in FIGS. **19**C and **19**D. Ring **382** can initially be positioned within arm **202** and coupled to link **264**, as shown in FIG. **19**E. Link **264** can couple with the ring **382** using any suitable technique, such as tying or the like.

As shown in FIG. **19**E, as the elongate shank **252** engages with arm **202**, clip **376** can be advanced, as indicated by arrow **383**, to couple with ring **382**. As illustrated in FIG. **19**F, as clip **376** engages with ring **382**, flexible arms **378** flex in a direction indicated by directional arrows Y and Z thereby increasing a width W; of passageway **380** in order to allow passage of ring **382** through passageway **380** of clip **376**.

Referring to FIG. **19**G, there is shown a top view of end face **158** of arm **202** where arm **202** can include a cuff pocket **384** having a pair of elongated openings **386** and **388** that intersect in the middle to form a cross. Cuff pocket **384** holds ring **382** such that ring **382** is general positioned in opening **386** prior to engagement with clip **376**. Cuff pocket **384** is configured such that as penetrator shank **252** engages arm **202**, clip **376** can enter opening **388** and engage with ring **382** as shown. Once clip **376** engages with ring **382**, ring **382**, which is coupled with link **264**, can detache from cuff pocket **384** while penetrator shank **252** remains engaged with clip **376**.

FIG. **20** shows an embodiment of a cuff and link assembly that may be used with various embodiments. Cuff **390** has a penetrator tip receiving end **392** and a tapered end **394**. Link **396** has two ends **398** (only one shown in FIG. **20**). An example of a preferred link material is expanded Polytetrafluoroethylene (ePTFE), more commonly referred to as teflon. ePTFE is particularly suited for use as the link material in the vessel closure devices described herein because of its low friction, high strength properties.

To assemble the link and cuff assembly, a length of link **396** is first threaded through cuff **390**. The end **398** of link **396** extending from penetrator tip receiving end **392** of cuff **390** is then heated so that end **398** of link **396** expands. Link **396** is then pulled through cuff **390** such that the expanded end portion **398** is seated in the interior tapered end **394** of cuff **390**.

In some embodiments it may be advantageous to provide multiple suture loops across the tissue opening. For example, closure of a large opening may require two three or more pairs of loops. To accommodate this, tissue closure devices can incorporate more than two arms.

Tissue locators envisioned herein may contain any number of arms. For example, tissue locators having four, six, eight, ten or more arms are possible. Independent of the number of arms, all of the arms can be essentially identical and positioned on the tissue locator so as to be radially spaced about the tissue opening. The arms can be equidistantly placed about the tissue opening or can have varying distances between them.

By using more arms, multiple suture links can be formed using the cuffs in the arms. For example, for any even number of arms, a number of links equal to half the number of arms can be formed, where each link spans between two of the cuffs. For example for tissue locators having four, six, eight, and ten arms, two, three, four, and five links can be formed, respectively. The links can be formed between diametrically opposed cuffs or between any of the cuffs, as discussed below. Each link and corresponding cuffs can be employed in any of the manners discussed above.

FIGS. **21**A through **21**D show one embodiment of a tissue locator **400** that incorporates four arms. Tissue locator **400** is similar to tissue locator **200** (see FIGS. **5**A-**5**D), except for the additional arms. That is, similar to tissue locator **200**, tissue locator **400** has a pair of arms **402***a* and **402***b* diametrically opposed to each other with respect to central axis **122**. However, unlike tissue locator **200**, tissue locator **400** also has a second pair of arms **402***c* and **402***d*, also diametrically opposed to each other with respect to central axis **122**. As such, there are four arms **402** arranged radially about central axis **122**, as particularly shown in FIGS. **21**B and **21**D. Similar to the embodiments discussed above, each arm **402** can include a penetrator receptacle **164** and a cuff **166** releasably positioned therein. Also similar to the tissue locators discussed above, each arm **402** can pivot about its distal end **152** between the retracted position, as shown in FIGS. **21**A and **21**B, and the deployed position shown in FIGS. **21**C and **21**D by distal movement of expander **188**.

FIGS. **22**A through **22**D show another embodiment of a tissue locator **410** that incorporates four arms **412** (**412***a*-**412***d*). Tissue locator **410** is similar to tissue locator **400**, except that instead of using expander **188** to deploy the arms, tissue locator **410** uses expander **232** that is moved proximally instead of distally to deploy the arms, similar to tissue locator **230** (see FIGS. **6**A-**6**D). As such, similar to arms **234** of tissue locator **230**, arms **412** are initially in a retracted position, as shown in FIGS. **22**A and **22**B, and can be pivoted laterally outward to the deployed position by proximal movement of expander **232**, as shown in FIGS. **22**C and **22**D.

Tissue locators **400** and **410** can be used with any of the tissue closure devices discussed or envisioned herein and penetrators **136** can be employed therewith in any of the manners discussed above. To take advantage of all four arms **402** or **412**, four penetrators **136** can be positioned within shaft **104**, with each penetrator **136** being substantially aligned with one of the arms so as to be able to advance into the four cuffs. Although only two and four arms have been discussed herein, it is appreciated that more than four arms can also be used, along with the same number of corresponding cuffs, penetrators, etc.

In many respects, a tissue closure device with four arms works in a similar manner as a tissue closure device with only two arms, such as those discussed above, except for the use of the four arms instead of two. For example, regardless of the number of arms used, the tissue locator can be inserted through the tissue opening with the arms in the retracted position; the arms can be deployed and positioned against the distal wall of the tissue; the penetrators can be advanced through the tissue wall until attached to the cuffs and thereafter withdrawn; suture links and/or the cuffs can be withdrawn with the penetrators; the arms can be retracted back to the retracted position so that the tissue closure device can be withdrawn from the tissue opening, and the withdrawn suture can be used to seal the tissue opening.

However, tissue closure devices having more than two arms can provide unique benefits over those that do not, and these benefits will be discussed below. For ease of discussion, reference numeral "**500**" will be used to delineate the arms when referring to the multiple arms below. In addition, each arm **500** will be referred to as "first" arm, "second" arm, "third" arm, "fourth" arm, etc., in a clockwise manner about central axis **122**. Each penetrator, penetrator receptacle, cuff, etc. that corresponds with the particular arm **500** will also be referred to using the same identifier (e.g., "first", "second", "third", and "fourth"). To help in the drawings, each of the items may also include a lower-case letter, appended to the reference numeral, corresponding to the identifier, with "a" representing the "first" identifier, "b" representing the "second" identifier, and so forth. Thus, the first, second, third, and fourth arms will have designations of "**500***a*", "**500***b*", "**500***c*", and "**500***d*", as shown in FIGS. **21**B and **22**B.

As noted above, a penetrator **136** can be associated with each of the four arms **500**. In some embodiments, penetrators **136** can be "paired" by being associated with a pair of cuffs linked together by a suture link in a similar manner to the embodiments discussed above. For example, if first and third cuffs are linked together by a suture link and second and fourth cuffs are linked together by a separate suture link, then first and third penetrators are considered to be paired with each other and second and fourth penetrators are considered to be paired with each other.

In some embodiments, each penetrator pair can be advanced and/or withdrawn independently from the other linked penetrator pairs. In other embodiments, each penetrator can be advanced and/or withdrawn independently from the other penetrators. To facilitate these options, the tissue closure device can have a plurality of penetrator actuation handles. Alternatively, the penetrator actuation handle can be divided into different portions, one for each penetrator or penetrator pair.

For example, FIGS. **23**A-D show an embodiment of a penetrator actuation handle **502** that can be used with either of tissue closure devices **410** or **412**. As shown in FIG. **23**A, penetrator actuation handle **502** can be divided into four separate penetrator actuators **504** (**504***a*-**504***d*). Each penetrator actuator **504** can be coupled with one of the penetrators **136** so as to direct the movements of the respective penetrator **136**. For example, first, second, third, and fourth penetrator actuators **504***a*, **504***b*, **504***c*, and **504***d* can be respectively attached to first, second, third, and fourth penetrators **136***a*, **136***b*, **136***c*, and **136***d*.

When it is desired to advance or withdraw a particular penetrator, the penetrator actuator corresponding to the desired penetrator can be advanced or withdrawn, respectively. For example, to advance first penetrator **136***a* distally without advancing the other penetrators, first penetrator actuator **504***a* can be distally advanced, as shown in FIG. **23**B. If two or more penetrators are to be moved concurrently, such as, e.g., any paired penetrators, penetrator actuators **504** corresponding to the desired penetrators can be used. For example, to concurrently advance first and fourth penetrators **504***a* and **504***d* distally, first and fourth penetrator actuators **504***a* and **504***d* can be advanced, as shown in FIG. **23**C. If all of the penetrators are to be moved concurrently, all of the penetrator actuators can be used. For example, to advance all of the penetrators distally at the same time, penetrator actuators **504***a*-**504***d* can be advanced, as shown in FIG. **23**D. Penetrator actuation handle **502** can be adapted to be used with any number of arms by simply dividing the handle **502** into the desired number of penetrator actuators **504**. Other penetrator actuators can also be used.

FIGS. **24**A-**32**C are schematic representations that illustrate examples of various link combinations and link nets that can be used to close tissue openings according to the present invention. In the examples, the ends of each link can extend into a cuff disposed within a penetrator receptacle in any of the manners discussed above. To close the tissue openings with any of the following link combinations and link nets, penetrators can be used in any of the manners discussed above to attach to the cuffs and pull the links proximally out of the body where they can be tightened, then tied off or clipped.

Although each link in FIGS. **24**A-**32**C is shown as extending in a generally shortest route between cuffs or between cuff and hub, Applicant notes that those figures are schematic representations to illustrate a particular manner of link and that the actual links may instead be longer and may take a circuitous route between the respective cuffs, if desired, similar to the various embodiments discussed above.

FIG. **24**A illustrates one embodiment of a link combination **510** that can be used with tissue closure devices having four arms, such as tissue locators **400** and **410**, discussed above. Link combination **510** includes two links **512** and **514** whose ends are attached to different cuffs. Links **512**, **514** can cross each other as they span across tissue opening **250** to link diametrically opposed cuffs. For example, in the depicted embodiment the first and third cuffs **166***a* and **166***c* are linked by first link **512** and the second and fourth cuffs **166***b* and **166***d* are linked by second link **514**. As such, correspondingly formed loops **512'** and **514'** can intersect across tissue opening **250** in a cross pattern when the opening **250'** is closed thereby, as illustrated in FIG. **24**B. Although first and second links **512** and **514** intersect each other, they can be unattached to each other and therefore free to longitudinally move independent of each other.

FIG. **25**A illustrates another embodiment of a link combination **520** that can be used with tissue closure devices having four arms. Similar to link combination **510**, link combination **520** includes two links **522** and **524** whose ends are attached to different cuffs. However, instead of being attached to diametrically opposed cuffs, the ends of each link **522**, **524** attach to cuffs on adjacent arms. For example, in the depicted embodiment the first and second cuffs **166***a* and **166***b* are linked by first link **522** and the third and fourth cuffs **166***c* and **166***d* are linked by second link **524**. As such, correspondingly formed loops **522'** and **524'** can span across tissue opening **250** without intersecting each other when the opening **250'** is closed thereby, as illustrated in FIG. **25**B. Link combination **520** may be especially useful for closing openings that are elongated, but may be used to close any type of tissue opening.

Alternatively, first and second links **522** and **524** can cross over each other as each link extends between its respective cuff, as depicted in link combination **530** in FIG. **26**A. In particular, first and second links **522** and **524** can be looped through each other, as shown in FIG. **26**A. As such, the correspondingly formed loops **522"** and **524"** can pull laterally against each other when tightened to close tissue opening **250"**, as illustrated in FIG. **26**B. Similar to links **512** and **514**, first and second links **522** and **524** can be unattached to each other and therefore free to longitudinally move independent of each other in either embodiment.

As noted above, each linked cuff pair can be attached to a different suture loop which can be closed about tissue opening **250** using one or more of the methods discussed above. For example, for link combinations **510**, **520**, and **530** shown respectively in FIGS. **24**A, **25**A, and **26**A, once arms **500** have been deployed and positioned against the distal surface of the tissue, any of the methods discussed herein can be performed for any of the links.

For example, for the embodiment shown in FIG. **24**A, any of the methods can be employed using linked first and third cuffs **500***a* and **500***c* and corresponding first and third penetrators to pull the corresponding link **512** proximally through the tissue and any of the methods can be employed using linked second and fourth cuffs **500***b* and **500***d* and corresponding second and fourth penetrators to pull the corresponding link **514** proximally through the tissue. In some embodiments, the same method can be used for both linked cuff pairs, and in other embodiments, different methods can be used for each linked cuff pair.

As discussed above, once links **512** and **514** have been pulled through the tissue, the corresponding suture loops can be tightened about tissue opening **250** to close the opening as shown in FIG. **24**B. In a similar manner, the linked cuff pairs shown in FIGS. **25**A and **26**A can also be attached to suture loops to tighten about and close tissue opening **250** using any of the methods discussed herein.

The methods can be employed in parallel (i.e., the pairs of penetrators corresponding to each linked cuff pair being advanced and subsequently withdrawn concurrently) or serially (i.e., each pair of penetrators being advanced and subsequently withdrawn at different times from each other) using, e.g., penetrator actuators **504** shown in FIGS. **23**A-**23**D.

It is appreciated that the above discussion of suture links can be adapted to be used with any number of suture links. For example, FIG. **27**A illustrates one embodiment of a link combination **530** that can be used with a tissue closure device having six arms. Link combination **530** includes three links **532**, **534**, and **536** whose ends are attached to different cuffs. First link **532** spans between diametrically opposed cuffs, while links **534** and **536** span between cuffs on either side of first link **532**. Specifically, first link **532** spans between first and fourth cuffs **166***a* and **166***d*, second link **534** spans between second and sixth cuffs **166***b* and **166***f*, and third link **536** spans between third and fifth cuffs **166***c* and **166***e*, as depicted in FIG. **27**A. As a result, correspondingly formed loops **532'**, **534'**, and **536'** can close tissue opening **520'** in the manner illustrated in FIG. **27**B. Similar to other embodiments discussed herein, first, second, and third links **532**, **534**, and **536** can be unattached to each other and therefore free to longitudinally move independent of each other. Other link combinations are also possible. For example, along with link **532**, links **534** and **536** can also span between diametrically opposed cuffs.

When using multiple suture loops or other type of filament loops to close a tissue opening, some or all of the loops can be coupled together if desired to form a filament or suture net that closes the opening in the tissue. By coupling filament or suture loops together, the resulting filament or suture net can provide a more complete closure of the tissue opening and can be used to assure the loops are positioned correctly during the closure procedure. FIGS. **28**A-**32**B illustrate various embodiments of net links that can be used with a tissue closure device to produce a filament or suture net.

In one type of suture net, the individual links can be rigidly secured to each other to form a net link. For example, FIG. **28**A illustrates one embodiment of a net link **550** that can be used with tissue closure devices having four arms. Net link **550** is similar to link combination **510** shown in FIG. **24**A, except that in net link **550**, links **512** and **514** are rigidly secured to each other at their point of intersection to form a central hub **552**. As a result, central hub **552** divides link **512** into two separate portions **512***a* and **512***b* and link **514** into two separate portions **514***a* and **514***b*. As such, net link **550** has four separate link portions **554***a*-**554***d*, consisting of link portions **512***a*, **512***b*, **514***a*, and **514***b*, each extending radially outward from central hub **552** to be secured to corresponding cuffs **166***a*-**166***d*. Links **512** and **514** can be secured to each other at hub **552** by adhesive, welding, fastener, or the like, or can be integrally formed together as a link assembly.

During use, each link portion **554** can remain attached to its corresponding cuff **166** when cuffs **166** are retracted proximally through the tissue by the penetrators, e.g., in a similar manner to that discussed above with respect to the method shown in FIGS. **11**A-**11**G. As a result, all of the formed suture loop portions corresponding to link portions **554** can be pulled proximally outward through the tissue while hub **552** remains distal of the tissue wall (e.g., within a blood vessel). This produces a suture net or web. When the suture ends corresponding to the suture net are tied off to close tissue opening **250'**, hub **552** can remain aligned with tissue opening **250'** as shown in FIG. **28**B, thereby ensuring that the suture loops of the suture web properly come together on the inside of the tissue, while also providing structural strength due to the securing of the individual links at hub **552**.

In another type of suture net, the suture loops can be loosely coupled together instead of being rigidly secured to each other. For example, FIG. **29**A illustrates an alternative embodiment of a net link **560** that can be used with tissue closure devices having four arms. Net link **560** is similar to net link **550**, except that individual links **512** and **514** are not rigidly secured to each other at their point of intersection. Instead, a ring **562** can be used to form the central hub where the individual links **512** and **514** intersect. Each link **512**, **514** can extend through ring **562** so the correspondingly formed suture loops **512'** and **514'** intersect one another where they pass through ring **562**, as shown in FIG. **29**B. Ring **562** can allow links **512** and **514** (and therefore, the correspondingly formed suture loops **512'** and **514'**) to move longitudinally with respect to each other while still intersecting at hub **562**. Ring **562** can be rigid or flexible. In one embodiment, ring **562** is at least large enough for cuffs **166** to pass therethrough.

In an alternative embodiment, ring **562** can be rigidly attached to one of the links **512** or **514** while the other link passes through ring **562** without being attached thereto. This can allow the link to which ring **562** is unattached to longitudinally move with respect to the link to which ring **562** is attached. Ring **562** can be comprised of a loop of suture or any other biocompatible material.

Net link **560** can be used to close a tissue opening in a similar manner as net link **550**. That is, each link portion can remain attached to its corresponding cuff **166** when the cuffs are retracted proximally back through the tissue by the penetrators. Alternatively, if ring **562** is large enough for cuffs **166** to pass therethrough, the method shown in FIGS. **12**A-**12**D can be used for either link **512** or **514**. That is, one or more of the cuffs **166** can become detached from the corresponding penetrator and be pulled across the opening and proximally through the tissue by being pulled by the cuff coupled to the opposite end of the individual link. To do so, the cuff can pass through ring **562** before passing proximally through the tissue. Regardless of the manner of use, suture loops **512'** and **514'** of the suture net formed from net link **560** can be pulled proximally outward through the tissue and tied off while loop **562** remains over the tissue opening **250'**, as shown in FIG. **29**B.

FIG. **30**A illustrates another embodiment of a net link **570** in which the links pass through ring **562**. However, instead of extending between cuffs on diametrically opposed arms, the individual links in net link **570** extend between cuffs on adjacent arms. For example, in the depicted embodiment, first and fourth cuffs **166***a* and **166***d* are linked by first link **572** and second and third cuffs **166***b* and **166***c* are linked by second link **574**. Because links **572** and **574** extend through ring **562**, however, links **572** and **574** extend inward towards each other as they pass between the cuffs, as shown in FIG. **30**A.

When cuffs **166** corresponding to links **572** and **574** have been pulled proximally through the tissue and corresponding suture loops **572'** and **574'** are tightened about tissue opening **250'**, the tightening force of each suture loop attempts to pull the suture loop away from the center of the opening and toward the corresponding adjacent penetrator pathway holes in the tissue.

However, while allowing each suture loop **572'** and **574'** some movement away from the center of opening **250'**, ring **562** prevents suture loops **572'** and **574'** from moving completely away from the center of the opening, as depicted in FIG. **30**B. Net link **570** may be especially useful for closing openings that are elongated, but may be used to close any type of tissue opening. If desired, ring **562** can have some elasticity to allow further movement of suture loops **572'** and **574'** away from each other with greater tightening force.

FIG. **31**A illustrates an embodiment of a net link **580** that can be used with a tissue closure device having six arms. Similar to net link **570**, net link **580** also includes a pair of individual links that attach to cuffs on adjacent arms and pass through a ring. However, because six arms are present, net link **570** can also have another link passing between the two unused cuffs on the two additional arms.

For example, in the depicted embodiment, first and second links **582** and **584** pass through ring **562** as they respectively extend between cuff pairs **166**a/**166**f and **166**c/**166**d. A third link **586** is positioned between links **582** and **584** and extends across tissue opening **250** between diametrically opposed cuffs **166**b and **166**e. Link **586** extends through ring **562**, although this is not required. That is, link **586** may or may not pass through the ring. As such, it is clear that net links can be used by themselves or in conjunction with other individual links or link combinations that are not a part of the net link.

Similar to net link **570**, when corresponding suture loops **582'** and **584'** are tightened about tissue opening **250'**, the tightening force of each suture loop **582'** and **584'** attempts to pull the suture loop away from the center of the opening and toward the corresponding adjacent penetrator pathway holes in the tissue, as shown in FIG. **31**B. The additional suture loop **586'** can provide additional closure across opening **250'**.

In some situations, portions of the tissue surrounding opening **250** may be hardened or otherwise impenetrable due to various causes, e.g., due to scar tissue. In those cases, one or more of the penetrators may be unable to penetrate through the tissue. Suture nets can be adapted to be used in those situations.

For example, after positioning a tissue locator over the opening in the tissue and extending the arms in one of the manners discussed above, it may become apparent during the penetration phase that one or more of the penetrators cannot penetrate through the tissue. For example, if during the use of penetrator actuation handle **502** (FIG. **23**A), one or more of the penetrator actuators **504** are unable to be completely advanced distally, this may signify that the penetrators corresponding to the un-advanced penetrator actuators are unable to penetrate through the tissue.

If the rest of the penetrators were allowed to continue distally through the tissue and attach to their corresponding cuffs, the un-advanced penetrators would not advance through the tissue and therefore would not attach to their corresponding cuffs. As a result, the links associated with the unattached cuffs would not become attached to the penetrators and would therefore not become attached to the suture loops coupled with the corresponding penetrators. Thus, the closure of the opening could be detrimentally affected. In one scenario, a portion of a suture loop could remain within a vessel, not tied off or attached to anything else.

To prevent this from happening, the tissue locator can be withdrawn from the body after it has been determined which penetrators cannot penetrate through the tissue and before any of the penetrators have attached to the cuffs. A suture net or web can then be formed and attached to the cuffs in the tissue locator corresponding to the penetrators that can penetrate through the tissue. The cuffs corresponding to the un-penetrating penetrators can be left unattached or can be removed from the arms. The tissue locator can then be re-inserted into the body and the suture net or web can be used to close the opening.

For example, let us assume that a tissue locator having six arms is used to attempt to position three suture loops about tissue opening **250** using links **590**, **592**, and **594** configured as shown in FIG. **32**A. After the tissue locator has been positioned over the opening and the arms extended, however, it becomes apparent during the penetration phase that the sixth penetrator cannot penetrate through the tissue. Before the other penetrators have been extended far enough to attach to their corresponding cuffs, the penetrators can be withdrawn back into the tissue locator, the arms rotated back to the retracted position and the tissue locator withdrawn through the opening and from the body.

The original three links can then be replaced by a net link **596** having five link portions **598**a-**598**e extending radially outward from a hub **599** to respectively attach to the first through fifth cuffs **166**a-**166**e corresponding to the penetrating first through fifth penetrators; the sixth cuff **166**f corresponding to the un-penetrating sixth penetrator can be left unattached or can be removed from the corresponding sixth arm, as shown in FIG. **32**B. As such, in the embodiment depicted in FIG. **32**B, only five of the six cuffs **166** are used to form net link **596**.

The tissue locator can then be re-inserted through the opening **250** and net link **596** can be deployed in one of the manners discussed above using only the penetrating first through fifth penetrators. The suture ends associated with net link can then be used to secure and close the opening as shown in FIG. **32**C.

It is appreciated that the suture nets discussed above can be adapted for use with tissue closure devices having any number of arms. It is also appreciated that suture nets and suture loops can be mixed and matched with each other in the same tissue closure device, as desired.

Although the discussion with respect to tissue locators has been directed to the use of two, four, and six arms and associated cuffs and penetrators, it is appreciated that the discussion can be applied the use of any number of arms and associated cuffs and penetrators. For example, three, or five or more arms may be used. In some embodiments, six, eight, ten, or more arms may be used. In some embodiments an odd number of arms may be used, e.g., where one or more cuffs have a plurality of suture ends extending therefrom. As such, the present invention encompasses the use of more than two needles and associated receptacles, cuffs, sutures, and the like. Also as a result, a wide variety of stitching patterns can be provided by such multiple loop probes.

Because the arms are radially spaced about the opening, multiple suture links can be formed as well as one or more suture nets using the cuffs in the arms. In general, for any even number n of arms, a number l of links equal to half the number of arms can be formed. For example for tissue locators having six, eight, and ten arms, three, four, and five links can be formed, respectively. The links can be formed between diametrically opposed cuffs or between any of the cuffs, in the manner discussed above. Similarly, any number of arms can be used in forming a suture net.

Although various embodiments of penetrators, penetrator receptacles, cuffs, means for releasably attaching the penetrator to the cuff, bights, knots, etc. have been discussed herein, it is appreciated that other configurations of said components are also encompassed by the present invention.

The present disclosure may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the disclosure is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. An apparatus for closing an opening in a body tissue, the apparatus comprising:

a shaft extending along an axis between a proximal end and a spaced apart distal end, the shaft having a size and configuration suitable for insertion through an opening in body tissue;

a first arm extending between a proximal end and a distal end, the distal end of the first arm being hingedly attached to or integrally formed with the shaft;

a second arm extending between a proximal end and a distal end, the distal end of the second arm being hingedly attached to or integrally formed with the shaft, the second arm being laterally spaced apart from the first arm, the first and second arms being movable between:

a retracted configuration in which the first and second arms are each aligned along the shaft, and

a deployed configuration in which the proximal end of each of the first and second arms pivot respectively about the distal end of the respective arm so as to extend laterally away from the shaft;

an elongate expander positioned within the shaft and having a first position axially separated from the first arm and the second arm and a second position contacting a portion of the first arm and the second arm, movement of the expander causing the first and second arms to move between the retracted and deployed configuration;

a flexible filament having first and second ends that are removably coupled with the first and second arms, respectively;

a first elongate penetrator positioned proximal of the first arm, the first penetrator being advanceable distally from the shaft to the first arm in the deployed configuration; and

a second elongate penetrator positioned proximal of the second arm, the second penetrator being advanceable distally from the shaft to the second arm in the deployed configuration.

2. The apparatus recited in claim **1**, wherein the proximal ends of the arms extend laterally away from the shaft in opposite directions in the deployed configuration.

3. The apparatus recited in claim **1**, wherein the expander is positioned within a lumen of the shaft.

4. The apparatus recited in claim **1**, wherein the expander is substantially conical.

5. The apparatus recited in claim **1**, wherein movement of the expander in the distal direction causes the proximal ends of the arms to laterally move to the deployed configuration.

6. The apparatus recited in claim **1**, wherein movement of the expander in the proximal direction causes the proximal ends of the arms to laterally move to the deployed configuration.

7. The apparatus recited in claim **1**, wherein the expander is threaded.

8. The apparatus recited in claim **1**, further comprising:

a third arm extending between a proximal end and a distal end, the distal end of the third arm being hingedly attached to or integrally formed with the shaft; and

a fourth arm extending between a proximal end and a distal end, the distal end of the fourth arm being hingedly attached to or integrally formed with the shaft, the fourth arm being laterally spaced apart from the third arm, the third and fourth arms also being movable between:

a retracted configuration in which the third and fourth arms are each aligned along the shaft, and

a deployed configuration in which the proximal end of each of the third and fourth arms pivot respectively about the distal end of the respective arm so as to extend laterally away from the shaft, the third and fourth arms also being caused to move between the retracted and deployed configurations by movement of the expander.

9. The apparatus recited in claim **8**, further comprising:

a second flexible filament having first and second ends that are removably coupled with the third and fourth arms, respectively;

a third elongate penetrator positioned proximal of the third arm, the third penetrator being advanceable distally from the shaft to the third arm in the deployed configuration; and

a fourth elongate penetrator positioned proximal of the fourth arm, the fourth penetrator being advanceable distally from the shaft to the fourth arm in the deployed configuration.

10. The apparatus recited in claim **8**, wherein the proximal ends of the third and fourth arms extend laterally away from the shaft in opposite directions in the deployed configuration that are different than the lateral directions of the proximal ends of the first and second arms.

11. The apparatus recited in claim **8**, wherein the first flexible filament forms part of a filament net having multiple ends that are each removably coupled with separate ones of the arms; and

each penetrator being positioned proximal of the respective arm, the penetrators being advanceable distally from the shaft to the respective arm in the deployed configuration.

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